A field performance and adherence study of point-of-use water treatment in Zambia and Pakistan

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Declaration of Own Work

I, Ameer Shaheed, confirm that the work presented in this thesis is my own. Where information has been derived from other sources, I confirm that this has been indicated in the thesis.

ABSTRACT

While point-of-use (POU) water treatment may be efficacious in laboratory or idealized intervention settings, its use as a strategy for delivering safer drinking-water is constrained by (1) relatively poor field performance compared with laboratory performance, (2) low adherence (correct, consistent, and sustained use), and 3) insufficient understanding of underlying behavioural barriers and drivers to adherence. A multi-site, mixed-methods longitudinal crossover trial was conducted, assessing two flocculent-disinfectant POU products: the Purifier of Water® ("PoW") and the new Pureit® sachet, in urban Zambia and peri-urban Pakistan. The aim was to evaluate field performance, different measures of adherence (chlorine residuals, used packet counts, and self-reported usage), and potential correlates of adherence over time.

(1) Pureit-treated samples had significantly higher chlorine residuals in both countries, though did not maintain minimum levels of free chlorine any longer, and had potentially weaker buffering capabilities than PoW. Field performance also varied significantly between study sites, and was sensitive to differences in adherence, measurements, and reporting accuracy. Qualitative feedback indicated a number of product-related weaknesses. (2) Adherence was generally low and declined over time in both countries, while untreated water consumption rose. Adherence was higher in Pakistan than in Zambia. Self-reported usage was considerably higher than observed measures. (3) A complex interplay was observed between drivers and barriers. The perceived need to treat water may have ultimately been purposive, based on circumstantial factors that influenced quality perceptions. Both products' adherence-related costs ultimately outweighed their benefits.

This study's findings underline the challenge in high POU adherence, the importance of carefully measuring field performance, and suggest that for POU to be consistently used – and thus deliver health impact – behavioural factors and added-value to the user should inform intervention and design strategies alongside effectiveness, even under short-term use conditions.

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7-8-6

To my mother, father, and sister, for their love, forbearance, and incredible support. This is more their accomplishment than mine.

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If you wan go wash, na water you go use

If you want cook soup, na water you go use

If your head dey hot, na water go cool am

If your child dey grow, water he go use

If water kill your child, na water you go use

Nothing without water!

Water, him no get enemy!

Fela Kuti

Water No Get Enemy

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List of Abbreviations

CDC	U.S Centers for Disease Control and Prevention
CDP	Coagulant Disinfectant Product
F.Cl	Free residual chlorine
GBD	Global burden of disease
HUL	Hindustan Unilever
HWT(S)	Household water treatment (and safe storage)
IRR	Incidence rate ratio
LMC	Low- and middle-income country
LSHTM	London School of Hygiene & Tropical Medicine
MDG	Millennium Development Goals
nbreg	Negative binomial regression
NGO	Non-governmental organization
OGB	Oxfam GB
OR	Odds ratio
POU	Point-of-use water treatment
PoW	Procter & Gamble's Purifier of Water®
Pureit	Hindustan Unilever's Pureit ® sachet
SDG	Sustainable Development Goals
T.Cl	Total residual chlorine
UN	United Nations
UNICEF	United Nations Children's Fund
WASH	Water, sanitation, and hygiene
WHO	World Health Organization
zinb	Zero-inflated negative binomial regression

Chapter 1. Introduction and Objectives

1.1 STUDY OVERVIEW AND RATIONALE

Access to adequate water and sanitation is a fundamental human right (UN, 2010), and together with safe hygiene practices, represents a cornerstone of public health and community development (Bartram and Cairncross, 2010). However, at least 663 million people lack access to an improved source of drinking-water (WHO/UNICEF, 2015), and as many as 1.8 billion may be exposed to water that is faecally contaminated (Bain et al., 2014). It is estimated that water, sanitation and hygiene (WASH) can prevent more than half of the global burden of diarrhoeal disease – over 842 000 deaths in low- and middle- income countries (LMCs) alone (WHO, 2014). WASH also plays a significant role in the transmission of several other water-related infections such as trachoma, guinea worm and schistosomiasis (Cairncross and Valdmanis, 2006), and can indirectly impact gender equality, education, and economic gains(Bartram and Cairncross, 2010). Access to safe water includes the provision of water in adequate quantities and sufficiently high quality(Cairncross and Valdmanis, 2006). While safe and consistent piped water remains the ultimate target for safe water provision (WHO/UNICEF, 2015), water treatment at the point-of-use (POU) is an interim method that can improve water quality where it is low yet available in sufficient quantity. POU methods include techniques that can be conducted at the household- or individual-level, such as boiling, filtration, flocculation, and chemical disinfection (WHO, 2007). This relatively recent addition to the field of water quality and public health has been shown to have a significant, if highly variable, impact in reducing diarrhoeal disease (Waddington et al., 2009; Wolf et al., 2014), and POU water treatment methods are widely promoted by NGOs, international agencies, and governments (Clasen, 2015).

However, despite over two decades of research and public health interventions, the impact, scope and scalability of POU water treatment are still uncertain. The key concern is the variable health impact observed in assessments (Clasen et al., 2007; Fewtrell et al., 2005; Waddington et al., 2009). POU studies require individual or household-level usage, include a wide range of methods, products, and study designs, and are implemented across several different environmental and social landscapes (Clasen, 2009). Ensuring that POU methods function as intended under everyday conditions of use is essential. Though a wide and growing range of POU methods and products are available, international guidance measures have only recently been developed (WHO, 2012, 2011a), and new products may undergo varying degrees of quality control and impact assessment. One of the central issues in the POU evidence base is adherence, or correct and consistent usage, which is unclearly defined, poorly and infrequently measured, highly variable across studies, and critical to health impact (Brown and Clasen, 2012; Clasen et al., 2007; Wolf et al., 2014). It has been suggested that limiting POU studies to deployment in high-risk, short-term usage contexts such as emergencies may avoid issues related to long-term adherence (Schmidt and Cairncross, 2009), however, estimates of even short-term adherence and health impact vary widely and are often very low (Brown et al., 2012; D. S. Lantagne and Clasen, 2012). Along with more and higher quality assessments of adherence, understanding the wide range of environmental, psychological, social, and other factors associated to POU adoption and adherence may also be critical (Clasen, 2015; Fiebelkorn et al., 2012). POU interventions must thus effectively and reliably improve water quality in "real world" settings, be accessible to at-risk populations, and be used correctly and consistently (Brown and Clasen, 2012; Clasen, 2015; Enger et al., 2013; Hunter et al., 2009). The many sources of variability in this field, including the wide range of methods, intervention designs, study settings, and individual-level behaviour change required, make it extremely challenging to accurately measure and assess POU impact.

The study presented in this thesis aims to add to the evidence base on POU field performance, adherence (correct and consistent usage over time), and determinants of usage, as well as providing the first assessment of a new product. It was designed, led, and assessed in a manner to address practical programmatic concerns while contributing to topical areas within POU research. A two-country, mixed methods longitudinal repeat-visit crossover study was conducted in urban Zambia (October -December 2012) and peri-urban Pakistan (December 2013 - February 2014), comparatively assessing adherence and field performance of two flocculant-disinfectant water treatment products, also known as coagulant disinfectant products (CDPs). The study was commissioned by Oxfam GB (OGB), whose primary objective was in assessing the field performance, usage and acceptability of the Pureit® sachet (henceforth referred to as Pureit), a new CDP developed by Hindustan Unilever Ltd (HUL) for use in short-term implementation activities such as emergency response. Procter & Gamble's Purifier of Water® (henceforth referred to as "PoW") was used as the standard for comparison. PoW is one of the best characterized and most commonly used CDPs (Chiller et al., 2006; Crump, 2005; Souter et al., 2003). Households in the urban compound selected in Zambia used a combination of standpipe water and shallow dug wells, and experienced seasonal cholera epidemics. The peri-urban location in Pakistan had experienced two large-scale floods within three years of the study. The primary data collection tool employed was a quantitative survey, administered on a weekly basis for eight weeks to over 200 households in both study sites. Households were randomly and equally assigned to one of the two products for four weeks, and then switched to the alternate product for another four weeks. Water samples, as well as information on observed and reported product usage were collected every week. A range of covariates was collected at different points in the repeat-visit survey, and included information on product feedback as well as potential drivers and barriers to usage. In addition, focus group discussions and semi-structured interviews were administered to a subsample of households to further probe product-related feedback, drivers, and barriers to adherence and expand on quantitative findings.

1.2 PRIMARY AIM AND OBJECTIVES

The primary aim of this study was: **to assess adherence and field performance related to PoW and Pureit in the context of short-term implementation and uptake**. This was addressed with three specific objectives, each of which is the focus of a separate "results chapter", concentrates on different components of the same overall experimental design and includes findings from both countries.

Objective 1: To assess the field performance of PoW and Pureit in the context of short-term implementation and uptake

Approach: The assessment was primarily based on water quality measurements and quantitative and qualitative product feedback. Water samples were collected from during unannounced weekly household visits if reportedly treated by users. Samples were tested across a range of physico-chemical parameters, focusing on free and total chlorine residual concentrations. Chlorine residual levels, post-treatment pH and user-reported time-since-treatment were assessed in light of international guideline values for water treatment in emergency and non-emergency situations. The survey included product-related feedback and scores from demonstrations of product usage. Focus group discussions and semi-structured interviews took place among a subsample of households, representing a wide range of product-related opinions in the study population. Qualitative findings related to product feedback were triangulated with quantitative results to inform a more holistic understanding of each product's treatment performance, across and between the two study sites.

Hypothesis: It was expected that Pureit would have a lower chlorine residual profile than PoW, lower organoleptic properties, and be preferred by users. Relatively greater chlorine demand was expected in Pakistan where the primary source was surface water, as opposed to Zambia where the standpipe water and groundwater were consumed.

Objective 2: To a) investigate short-term adherence to PoW and Pureit, and b) to evaluate commonly-employed adherence measures

Approach: Analysis focused on non-parametric hypothesis tests and regression models. A range of adherence measures were examined for trends over time, differences between the two products, and between subgroups of each study population. Findings were also compared between the different measures. Adherence data was collected upon every weekly visit, and included self-reported frequency of product usage (used sachets since the last visit), enumerator-observed sachet usage, as well as the presence of reportedly treated water samples and levels of detectable chlorine. Observed weekly sachet usage was also used to estimate daily usage and per capita consumption of safe water. Findings were compared and contrasted between countries.

Hypothesis: Adherence was expected to a) reduce over time in both study sites, b) be higher during exposure to Pureit, c) differ within certain subpopulations of each study site, and d) be greater in self-reports than in observed measures.

Objective 3: To explore correlates of adherence to PoW and Pureit in short-term use

Approach: Exploratory regression analysis was employed to assess factors correlated to weekly observed sachet use in each study site. Covariates were selected based on a review of the WASH-specific behaviour change literature. Findings from qualitative feedback and field observations related to drivers and barriers to usage were compared and contrasted to quantitative results. The interpretation of these findings was discussed in light of WASH-related behaviour change theories.

Hypothesis: Adherence over time was expected to be correlated to a range of contextual, psychosocial, and technology-related factors at multiple levels of influence. No *a priori* assumptions were held about the relative weight of various factors that might affect adherence.

1.3 PROJECT BACKGROUND

This thesis examines findings from a multisite assessment of adherence to and field performance of two flocculant-disinfectant POU products. The study was commissioned by Oxfam GB (OGB) to assess the acceptability, adherence, and performance of a new coagulant-disinfectant product for use in their programmes, particularly for short-term usage in post-emergency and outbreak contexts.

Hindustan Unilever Ltd. (HUL) is the Indian affiliate of Unilever International Ltd, one of the world's largest consumer goods companies. Pureit® is a HUL brand focussing on household water treatment, most notably water filtration units. Pureit's most recent product is the Pureit sachet® (referred to as Pureit in this thesis), a CDP intended for usage at the household-level. It is intended to be a low-cost commercial product for everyday use, and also available for humanitarian relief efforts. It is similar to Procter & Gamble's Purifier of Water® (PoW), previously known under the brand name PUR® (Souter et al., 2003). Pureit's advertised competitive advantage was a slightly shorter treatment time and more palatable taste than other CDPs on the market, most notably PoW.

HUL approached OGB regarding the potential use of Pureit in their humanitarian activities. OGB agreed to facilitate an independent investigation to inform their decision. HUL's main role was in providing the funds to OGB for the investigation, providing Pureit supplies to the investigators, and answering any technical queries within the limitations of their proprietary reservations. HUL did not have any control over OGB's dissemination of funds, in the selection of investigators, or in the investigations themselves, and all contractual agreements were made independently between OGB and the investigators.

OGB approached the Université Laval in Quebec, Canada, to first conduct an efficacy assessment of Pureit's performance under controlled laboratory settings (Marois-Fiset et al., submitted). Dr Caetano Dorea was the Principal Investigator, and assessed Pureit's efficacy across a range of challenge settings in artificial and natural water sources, using WHO and CDC guidelines for chlorinated water treatment (CDC, 2000; WHO, 2011b). This was as a confirmatory step to HUL's own efficacy assessments, which included certification by the Indian Food and Drug Administration (*R. Venkataraghavan, Hindustan Unilever, personal communication, Appendix A2*). OGB approached the London School of Hygiene & Tropical

Medicine (LSHTM) to conduct an evaluation of field acceptability, adherence, and performance, subject to the results from the efficacy assessments at Université Laval. Dr Joe Brown was the Principal Investigator from LSHTM. The author led the implementation, data analysis, and drafting of the field evaluation, working as a consultant for OGB.

Employing a longitudinal, mixed-methods repeat-visit crossover study design allowed us to carefully assess the performance, acceptability and uptake of the Pureit sachet, using the Purifier of Water (PoW) as a standard for comparison, PoW is the most widely reviewed CDP on the market (Chiller et al., 2006; Crump, 2005; Souter et al., 2003), and the main CDP employed by OGB prior to this study (*N Bazezew, OGB, personal communication*). The design employed allowed us to evaluate the new product, while seeking to add to the literature on POU adherence and field performance.

1.4 PRODUCT OVERVIEW

CDPs have the distinct advantage of combining several water treatment methods, including microbial pathogen reduction, turbidity reductions, and delivery of a post-treatment free chlorine residual (WHO, 2002). They are described as replicating the operations of a centralized water treatment plant in a sachet (Clasen, 2009). CDPs are well suited to humanitarian relief operations, particularly in high turbidity settings with high microbial contamination (Colindres et al., 2007; Doocy and Burnham, 2006; D. Lantagne and Clasen, 2012). They are among the most efficacious POU methods on the market (WHO, 2002) and can also reduce arsenic contamination(Souter et al., 2003). However, they are also among the most complex to use, require considerable effort, relatively long treatment times (averaging between 25-30 minutes), careful measurements of water volumes per sachet, and as with all chlorine products, can leave a strong taste and smell (Aquaya, 2005).

CDPs' dual action consists of a) coagulation, flocculation and precipitation (turbidity reduction), and b) microbial disinfection. In the first step, chemicals such as aluminium or iron-based salts destabilize colloidal particles in water (suspended solids causing turbidity), which precipitate, accumulating to form larger "flocs" of solid matter that eventually settle at the bottom of the water container (Edzwald, 2011; WHO, 2002). This greatly reduces water turbidity, and can have significant effects on microbial reductions. It is a key component of centralized municipal water treatment, though is also practiced at a community level using aluminium sulphate (alum)(WHO, 2002). The second component consists of microbial disinfection and typically uses a chlorine-based active compound, such as calcium hypochlorite (Clasen, 2009; WHO, 2002). Uninhibited suspended solids can greatly reduce the microbial effectiveness of chlorine (Edzwald, 2011; WHO, 2011b). Reducing turbidity allows a far more controlled and predictable release of chlorine. This is typically combined with a buffering agent to control the pH-variable reactions of chlorine in drinking-water (Edzwald, 2011).

Pureit contains the same coagulant (ferric sulphate) and chlorine-based disinfectant (calcium hypochlorite) as PoW. Its most significant departure from PoW is the presence of a chlorine-quenching agent, the details of which were not shared with the investigators due to HUL proprietary concerns. Pureit is intended to release a high initial dose of chlorine to induce maximum microbial removal, followed by the delayed action of a chlorine-quenching agent to reduce the free chlorine concentration with the intention of improving taste acceptability. Pureit's developers approximated initial free chorine concentration to be between 2 - 4 mg/L, dropping to 0.5 mg/L between 2 - 5 hours post-treatment due to the chlorine quenching agent. While specifying that concentrations were subject to different source water conditions, water was intended to be safe to consume for 48 hours if safely stored (*R. Venkataraghavan, Hindustan Unilever, personal communication*). Each 2.5 g sachet is capable of treating 10 L of water. Its usage follows similar steps to other sachet type POU water treatment products (e.g. WaterMaker, P&G Purifier of Water, Bishan Gari), namely: manual stirring (2 minutes), settling (20 minutes), and cloth filtration. According to the product's instructions, treated water should be ready to drink after the filtration step (i.e. after a 22 minute total disinfection contact time) and taste should improve within 1 hour. Tests conducted within HUL and by the Indian Food and Drug Administration *R. Venkataraghavan, Hindustan Unilever, personal communication.* The efficacy assessments at Université Laval found a minimum of 4 log reductions in bacterial indicators across a range of ambient and challenge water conditions (Marois-Fiset et al., submitted).

PoW was developed by Procter & Gamble (P&G) in collaboration with the US Centers for Disease Control and Prevention (CDC). It uses calcium hypochlorite for disinfection, ferric sulfate for coagulation, and also contains a buffer made from clay and a polymer to help control the reaction of the chlorine disinfectant in water (Doocy and Burnham, 2006). Studies of PoW's efficacy indicate more than 6 log reductions across a relatively wide range of pathogenic bacteria and indicator of faecal contamination (including agents of cholera, typhoid fever, and enterotoxic *E. coli*), greater than 4 log reductions in intestinal viruses (including rotavirus and poliovirus), and greater than 3 log reductions of protozoan oocysts (including *Giardia* and *Cryptosporidum* species) (Souter et al., 2003). The product comes in a 4 gram sachet that treats 10L of water (Aquaya, 2005). Table 1.1 and Figure 1.2 illustrate the main steps in product usage.

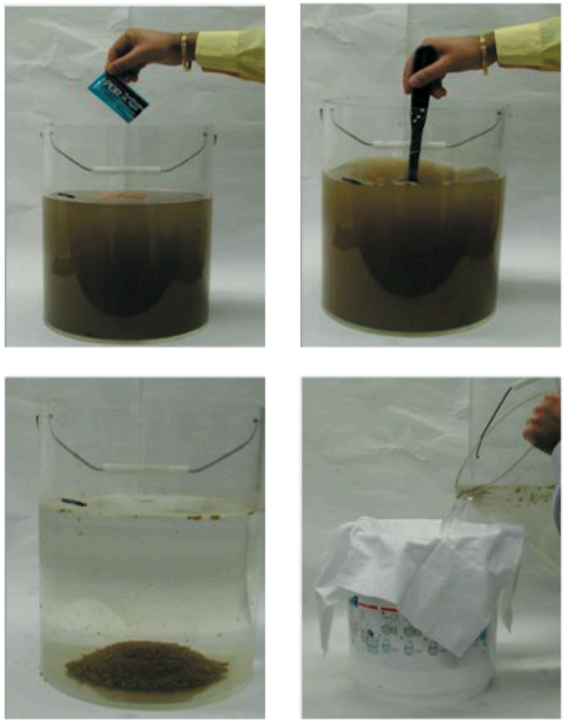
Table 1 1: Key differences between the Purifier of Water (PoW) and Pureit

Key usage features	PoW	Pureit	General steps for both products
Volume of water treated / sachet	10L	10L	➔ Measure out 10L of water ➔ Add sachet contents and stir the appropriate time ➔ Wait for flocculation, coagulation, and appropriate contact time (N.B the order of this step and the next differ by product) ➔ Filter water out into another container, using a cotton cloth to capture the solid matter
Stirring time	5 min	2 min	
Contact time (waiting time during disinfection)	25 min	20 min	
Order of steps	Stir, filter and wait for disinfection	Stir, wait for disinfection, and filter	

Figure 1 1: Product overview

Pureit sachet

Demonstration of PoW use, also applicable to Pureit



PoW sachet

1.5 THESIS FORMAT

This thesis is presented in "research paper style" as per Section 15.5 (4) of the 2014-2015 LSHTM Research Degrees Handbook. The Handbook notes that this style of manuscript is expected to be along the "book - research papers continuum". This is an appropriate definition for the three "results chapters" of this thesis, which are each in broad research paper form, and require further changes prior to submission. A greater level of detail was maintained for the purposes of this thesis, and each chapter's Results section was divided by country. References to other chapters will also be removed in the publication form. However, each chapter is held together by a single Introduction, Methods, and Discussion section, addressing the results as a whole. The journals outlined in the linking material preceding each results chapter are tentative, and the structure of each chapter will be amended based on the final selection.

The remainder of this thesis is presented as follows:

- Chapter 2 reviews key background literature. It sets POU within the wider context of WASH coverage and impact, and outlines different perspectives regarding water quality and POU interventions in the literature. It subsequently focuses on the three key aspects investigated in this thesis, namely POU effectiveness, adherence, and factors determining adherence.
- Chapter 3 summarizes the general methodology employed in project implementation as well as data management and analysis.
- Chapter 4 is the first results chapter, drafted in paper form. It addresses Objective 1, focusing on both products' field performance.
- Chapter 5 is the second results chapter, addressing Objective 2, focussing on adherence to the two products.
- Chapter 6 is the third and final results chapter, addressing Objective 3, focussing on correlates of adherence.
- Chapter 7 presents a general discussion, critically examining the key findings of this thesis, discussing them in light of the current literature, and suggesting areas for future research.

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Chapter 2. Literature Review

2.1 POINT-OF-USE WATER TREATMENT IN CONTEXT

2.1.1 Overview of the health and non-health impacts of WASH

Point-of-use (POU) water treatment represents a class of interventions that treat and maintain the microbial quality of water in a decentralized, small scale manner suitable for individual- or household-level usage (Clasen, 2009). While POU can refer to systems that are more appropriate for high-income settings, such as UV irradiation, membrane filtration or indirect potable water reuse (Bell and Aitken, 2008; Zhou and Smith, 2002), it is associated with simpler methods in the literature on public health in developing countries, where it is also referred to as household water treatment (HWT), or more holistically, household water treatment and safe storage (HWTS) (WHO, 2007). This manuscript uses the term in reference to the latter. POU methods fall within the broader category of water quality interventions, which, in turn, are part of the wider field of Water, Sanitation, and Hygiene (WASH). Access to adequate water, sanitation, and hygiene (WASH) addresses many basic human needs, providing a wide range of health and non-health benefits, comfort, and dignity (Bartram and Cairncross, 2010; WHO/UNICEF, 2015). Though including a wide range of different methods and products, WASH interventions address many of the same transmission pathways (Cairncross and Valdmanis, 2006), and relate to correlated aspects of everyday life.

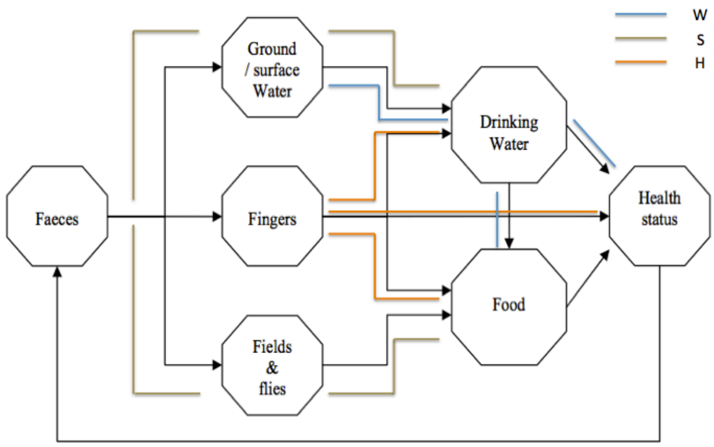
The Bradley classification (Table 2.1) of water-related infections divides them into four categories: waterborne, water-washed, water-based, and those related to water-related insect vectors(Cairncross and Valdmanis, 2006). Waterborne diseases are the most commonly associated with WASH, pertaining to pathogens that live in ingested water and mostly originate in human faeces, including several species of viruses, protozoa, and bacteria. Water-washed/water-scarce diseases arise most commonly when a lack of water for hygiene leads to infection, including trachoma-induced blindness (Stocks et al., 2014). Water-based infections occur where transmission of the pathogen is via an aquatic intermediate, as it does in schistosomiasis (Grimes et al., 2014). Diseases concerned with water-related insect vectors occur when transmission is through insects that spend a portion of their lives in the water, such as with dengue, or malaria (Cairncross and Valdmanis, 2006). Sanitation also plays an important role in soil-transmitted infections (Ziegelbauer et al., 2012), and fly control(Emerson et al., 2004).

Infectious diarrhoeal disease is one of the major public health concerns related to WASH, and inadequate coverage of safe water, sanitation, and hygiene practices account for a significant proportion of its global burden (Prüss et al., 2002; Wolf et al., 2014). WASH interventions represent the major primary and secondary barriers to infection along the faecal-oral transmission pathway (Figure 2.1), which accounts for the vast majority of infectious diarrhoea (Prüss-Üstün et al., 2008). This diagram is also known as the "F-diagram"(Wagner and Lanoix, 1959), given the central role of fluids (e.g water), fomites (e.g flies), fingers (e.g contact), and fields (e.g soil) in transmission. Safe excreta disposal through adequate sanitation is the most direct and earliest barrier to prevent transmission. Personal-, food-, and environmental hygiene address a number of pathways that prevent entry of pathogens via physical contact. Water in adequate quantities can be used for hygiene practices as well as for consumption, while water quality improvements prevent disease transmission through drinking-water, and in the use of water in preparing food (Figure 2.1).

The most recent review at the time of writing estimates that at least 58% of the total burden of diarrhoea may be averted through WASH interventions, amounting to 842,000 deaths from 145 LMCs (WHO, 2014a). The inadequate quality and quantity of water was estimated to account for 502,000 deaths, inadequate sanitation for 280,000, and 297, 000 due to inadequate hygiene practices (the combined estimate of 842,000 accounts for exposure to multiple risk factors) (WHO, 2014a). There is also compelling evidence linking adequate WASH, via diarrhoeal diseases, to reductions in the burden from several other outcomes including under-nutrition (Dangour et al., 2013), environmental enteropathy (Humphrey, 2009), pneumonia(Schmidt et al., 2009), and mortality and morbidity in HIV positive populations (Peletz et al., 2012).

WASH interventions are also related to a wide range of non-health outcomes. Diarrhoea-related malnutrition can affect school performance and delay entry to the market, leading to as much as 9% of gross domestic product (Bartram and Cairncross, 2010). The time spent seeking off-plot sanitation and water supplies has been estimated as amounting to USD 63 billion(Bartram and Cairncross, 2010). Water collection at a substantial distance from the house greatly reduces the amount of water used at the household-level(Cairncross and Valdmanis, 2006), reducing quantities available for hygiene and leading to greater risks of diarrhoea (Wang and Hunter, 2010). Helminth infections, strongly associated with sanitation, can also cause stunting and impaired cognitive function, further affecting economic productivity(Strunz et al., 2014). Improved sanitation facilities also impact on gender equality, affecting female school attendance, and safety and convenience of women seeking off-plot sanitation (Freeman et al., 2012; Garn et al., 2013).

Figure 2 1: Faeco-oral transmission pathways and points of action across water quality, hygiene, and sanitation interventions (W=Water, H=Hygiene, S=Sanitation)*



adapted from (Waddington et al., 2009)

Table 2 1: Bradley classification of water-related infections

Transmission route	Description	Disease group	Examples
Waterborne	The pathogen is in water that is ingested	Faeco-oral	Diarrhoeas, dysenteries, typhoid fever
Water-washed (or water-scarce)	Person-to-person transmission because of a lack of water for hygiene	Skin and eye infections	Scabies, trachoma
Water-based	Transmission via an aquatic intermediate host (e.g snails)	Water-based	Schistosomiasis, guinea worm
Water-related insect vector	Transmission by insects that breed or bite near water	Water-related insect vector	Dengue, malaria, trypanosomiasis

adapted from (Cairncross and Feachem, 1993)

2.1.2 Water, sanitation and hygiene coverage

Great strides have been made in access to water, sanitation, and hygiene coverage, and in reductions to the diarrhoeal disease burden. However, important gaps remain, largely within the populations that are hardest to reach and the most vulnerable (Gill et al., 2013; WHO/UNICEF, 2015). Diarrhoeal diseases have fallen sharply since the earliest global burden of disease (GBD) estimates, from 2.5 million deaths in 1990 (Kosek et al., 2003) to 1.3 million deaths in 2013 (Naghavi et al., 2015). However, this still represents a highly significant burden, and the majority of the burden rests with populations in Africa and Asia (Walker et al., 2013), with only five countries representing nearly half of global under-5 mortality(Bhutta et al., 2013). The greatest risk is shouldered by young children under the age of 5, amongst whom diarrhoeal disease and pneumonia still represent the leading causes of infectious disease (Walker et al., 2013).

The Joint Monitoring Programme for Water Supply and Sanitation (JMP) is the World Health Organization (WHO) and UNICEF collaborative agency tasked with monitoring global progress towards the Millennium Development Goal (MDG) target 7C: to "[h]alve, by 2015, the proportion of the population without sustainable access to safe drinking water and basic sanitation" (WHO/UNICEF, 2014). Coverage was estimated based on definitions of water sources and sanitation technology, broadly divided into "improved" and "unimproved" technologies (ibid). The target for safe drinking water was met in 2010, well in advance of the expected date. By the end of the MDG era in 2015, 2.6 billion people had gained access to an "improved" water source since 1990, and 91% of the global population were considered to be covered (WHO/UNICEF, 2015).

Despite the encouraging progress in improved water source coverage, over 663 million people still lacked access to an improved water source in 2015, and stark disparities in coverage remained (ibid). The lowest coverage was observed in the countries designated by the United Nations as the world's least developed countries (WHO/UNICEF, 2015). Within countries, most of the gains in access have been in urban areas (and mostly through access to piped water), indicating that the least served populations are rural and marginalized urban populations (e.g slum dwellers, low-income minority groups). Furthermore, the indicators employed by the JMP have been criticised for being based on physical structures as opposed to the quality or maintenance of sources (Bain et al., 2014; Shaheed et al., 2014a; Wolf et al., 2014). Post-source faecal contamination has been demonstrated in several papers (Bain et al., 2014; Levy et al., 2008; Shaheed et al., 2014b; Wright et al., 2004), and a recent systematic review of drinking water quality concluded that as many as 1.8 billion people use a source of water that is faecally contaminated, and that at least 10% of the world's "improved" sources would fall within a high risk category (Bain et al., 2014). The use of emergency water treatment may also play a more significant role in light of extant threats from outbreaks, increasing in some cases, as observed in cholera in Africa (Gaffga et al., 2007), and climate change-related natural disasters and seasonal changes (Costello et al., 2009; Hunter, 2003; WHO, 2009). In light of these issues, decentralized, household-level systems such as POU water treatment methods have the potential to increase safe water coverage among populations still lacking access to improved sources, those with improved sources of low or variable microbial quality, and those requiring short-term, emergency access to safe water.

2.1.3 Resource limitations

WASH is accorded a relatively low priority at the international and national level (Cairncross et al., 2010; UNESCO, 2009; WHO, 2014b). Funding is modest compared to other major infectious diseases, remaining largely stagnant or even decreasing in certain measures (WHO, 2014b). Political will, policy and budget-level priorities are just as critical as funding, demonstrated by the significant progress made by some of the world's poorest countries, such as Benin and Ethiopia (Cairncross et al., 2010). The multidisciplinary nature of WASH means that implementation, responsibility, and resource allocations can be unclear and fragmented (Bartram and Cairncross, 2010). Institutional fragmentation and poor coordination at the national level further exacerbate the issue. Though it spans major sectors including water, health, civil engineering, and urban planning, the potential scope of policy actions that could take place across these various sectors has been described as often remaining unrealized and poorly defined, failing to maximize on potential synergies (Eisenberg et al., 2012). Suggested priorities to address the gap in access and coverage of adequate WASH include further hard and soft support, prioritization at the national and international level, improved coordination between and within sectors, and further research on the specific interventions and methods that may most effectively increase coverage and impact (Cairncross et al., 2010). These barriers also provide further support for advocates of POU methods, as a means to help users of low-quality water supplies gain access to safe water, in a more efficient, easily mobilized, decentralized manner, aided in part by private sector mobilization and market forces.

2.1.4 Overview of water quality and POU interventions in the public health literature

Despite significant improvements in access to water, sanitation, and hygiene, important regions and subpopulations remain uncovered, largely within the hardest to reach and most vulnerable demographic groups. There are also significant challenges in funding and policy-level prioritization, as well as implementation. Much of the current WASH research focuses on how to help reach the achievable, if challenging, goal of global and sustainable coverage. Compelling evidence on how to effectively bring WASH coverage to scale could maximize the use of the available resources, and help garner further support. The best manner in which to improve coverage within the different components of WASH (including water quality, water supply, sanitation, and hygiene) is however subject to considerable debate. This section summarizes major findings relating to the relative impact of water quality and POU interventions.

Esrey and colleagues (1991) conducted the first systematic review of WASH interventions, finding water quality interventions to have led to a median diarrhoeal disease reduction of 17%, compared with 27% for water supply, 22% for sanitation, and 33% for hygiene interventions (Esrey et al., 1991). Improved water quantity was considered to be more effective than water quality as it was also associated with improved hygiene, and thus also addresses "water-washed" and "water-scarce" diseases (Table 2.1). Sanitation and hygiene were noted to be more effective at preventing diarrhoea given their wider influence on transmission pathways. This was supported by VanDerslice and Briscoe (1993) who suggested that household-level contamination did not present significant health risks as it was merely recycling pre-existing contamination, whereas source-level contamination introduced new pathogens (VanDerslice and Briscoe, 1993). However, these studies did not include household-level water quality interventions, and a growing body of evidence suggested that source-level supply and treatment interventions were vulnerable to post-source contamination(Jensen et al., 2002; Wright et al., 2004).

Post-source contamination and the challenge of rapidly scaling access in low-income settings led to a growing interest in water quality improvements at the household-level as a more cost-effective, interim solution, before piped water could be provided (Eisenberg et al., 2012). Though certain types of POU treatment, like boiling water and simple cloth filtration have been practiced traditionally for centuries (Rosa and Clasen, 2010), POU rose to prominence with a small number of early reviews focussing on disinfectants and safe storage (Mintz et al., 1995). The U.S Centers for Disease Control (CDC) and the Pan American Health Organization (PAHO) also began investigating the impact of dilute sodium hypochlorite to combat the cholera epidemic in Latin America (Lantagne, 2008) POU studies rose steadily throughout the late 1990s through to the first decade of the 2000s, using a wide variety of technologies and showing an equally wide, though often highly significant impact on diarrhoeal disease morbidity(Brown et al., 2008; Chiller et al., 2006; Doocy and Burnham, 2006; Lule et al., 2005; Quick et al., 2002; Reller et al., 2003). The main methods implemented were chlorination, flocculation, filtration, solar disinfection, and boiling (Clasen, 2015, 2009). The first major POU technology review also identified these five technologies as the most reliable and effective (WHO, 2002). The early 2000s saw considerable political support for POU, as a potentially highly efficacious, decentralized, cost-effective method to meet the MDGs and the lack of coverage that significantly affected the most vulnerable (Clasen et al., 2007; Eisenberg et al., 2012; WHO, 2007).

Further reviews were conducted in the early 2000s, representing more advanced methods of assessment (Clasen et al., 2014). Prüss and colleagues conducted a WASH-specific estimation, finding over 44% reductions in water quality interventions, greater than decreases due to water supply (20%), sanitation (37%), and hygiene (35%) (Prüss et al., 2002). This was followed by WASH- and POU-specific systematic reviews (Fewtrell et al., 2005), meta-analyses (Waddington et al., 2009) and Cochrane reviews(Clasen et al., 2007). Fewtrell and colleagues (2005) Clasen and colleagues (2007) and Waddington and colleagues (2009) respectively found 35%, 47%, and 44% average reductions in diarrhoeal disease due to POU interventions, as compared to 11%, 27%, and 21% in source-level quality improvements, respectively. However, these findings were accompanied by the identification of significant weaknesses in many of the studies included in these reviews (Clasen et al., 2007; Fewtrell et al., 2005; Schmidt and Cairncross, 2009; Waddington et al., 2009), raising doubts upon the overall impact of POU interventions(Schmidt and Cairncross, 2009).

The central issue observed in many of the POU reviews was the wide heterogeneity observed in impact measures, often from similar interventions. Many studies that were included were of medium to low quality (Clasen et al., 2007; Fewtrell et al., 2005; Waddington et al., 2009). Most notably, few blinded trials have been published, and those available have revealed no significant health impact, in sharp contrast to the average effects observed in reviews (Boisson et al., 2013; Jain et al., 2010; Kirchhoff et al., 1985). The role of adherence to the intervention was also unclear, and measured in relatively few studies (Clasen et al., 2007). Many of the studies that assessed adherence often found less than 50% of the target population to be regular users (Boisson et al., 2010; Luoto et al., 2011; Rosa et al., 2014), while others found strong effect sizes despite low adherence (Kremer et al., 2008; Reller et al., 2003) or microbial contamination in a significant proportion of water samples (Garrett et al., 2008; Tiwari et al., 2009). It has been argued that many of these issues provide evidence that the high self-reported diarrhoeal impacts were largely due to bias (Engell and Lim, 2013; Schmidt and Cairncross, 2009). Theory-driven arguments have also drawn attention to the small part of the faecal-oral transmission pathway addressed by water quality interventions, as well as the small role of within-household transmission(Cairncross et al., 1996).

This more critical view of the POU evidence base led a 2010 systematic review of the WASH impact to retain Esrey and colleagues' (1991) more conservative estimate of a 17% reduction in diarrhoea (Cairncross et al., 2010). Engell and Lim (2013)'s systematic review of the health impact of WASH interventions only included water quality studies from the few blinded trials, influencing the GBD 2010 study to conclude that water and sanitation had considerably lower impacts than previously estimated(Engell and Lim, 2013; Naghavi et al., 2015). These findings were widely criticized (Clasen et al., 2014; Prüss-Ustün et al., 2014; Watts and Cairncross, 2012; Wolf et al., 2014), and followed by a series of studies published in 2014 seeking to provide further clarity to the issue, using an updated and inclusive review of the evidence base, rigorous assessment methods, and accounting for bias (Clasen et al., 2014; Prüss-Ustün et al., 2014; WHO, 2014a; Wolf et al., 2014). Wolf and colleagues' meta-regression and systematic review was highly inclusive, comprising a wide range of observational and intervention trials, robust analytical methods, and a conservative counterfactual (Wolf et al., 2014). The pooled estimates for water quality interventions indicated a 34% decrease in diarrhoeal disease (ibid). Consistently treated piped water on the premises was associated with the largest health impact at the community-level, and all categories of POU intervention included were also associated with a significant health impact (ibid). In addition, they adjusted their estimates for potential bias from open trials and non-objective outcomes (Wood et al., 2008), applying a conservative correction factor of 30%. After this adjustment however, only filtration still showed a strong impact (34% reductions, and 45% when combined with safe storage) (Wolf et al., 2014). Filtration has been widely found to be among the most effective POU intervention (Clasen et al., 2007; Hunter, 2009; Waddington et al., 2009). Wolf and colleagues also found that combining POU with hygiene education and/or improved sanitation had an added effect than water quality interventions alone(Wolf et al., 2014).

The evidence base may be interpreted as suggesting that certain POU methods may be highly effective in certain situations (Brown et al., 2008; Clasen et al., 2015; Doocy and Burnham, 2006), though studies are also subject to considerable bias (Schmidt and Cairncross, 2009). It further suggests that there is currently too much "noise" to the "signal", and that future studies need to improve upon their designs and focal areas to understand the conditions under which POU may be most effective. It is unlikely that a single generalizable impact estimate can be found, given the number of context-specific factors involved, including local environmental pathogen distributions, the relative contribution of different routes of transmission, seasonal fluctuations, intervention-specific effectiveness, adherence, and several other factors (Clasen, 2015; Eisenberg et al., 2012). WASH studies general face several difficulties at both the level of the outcome (e.g health measures) as well as of exposure (e.g adherence to soap, latrines, and POU products), and better characterising these are important aspects to improving the evidence base(Blum and Feachem, 1983). Outcomes could be improved by focusing on more accurate and objective health and non-health measures; shifting towards more of a systems approach to analyse WASH; including more multidisciplinary research; and employing study designs clustered at the community-level (Blum and Feachem, 1983; Cairncross and Valdmanis, 2006; Eisenberg et al., 2012). Assessing exposure is a particular challenge for interventions requiring individual-level behaviour change, and includes the need for careful measurements of adherence. Such methods need to focus on accurate measurements while avoiding the significant sources of potential bias, and could include more objective indicators, passive monitoring, and "opportunistic" study designs of existing WASH systems (Eisenberg et al., 2012; Waddington et al., 2009; Wolf et al., 2014).

2.2 CRITICAL GAPS IN THE POU LITERATURE

More than two decades of research and several systematic reviews have shown that POU, together with other WASH interventions, can provide numerous benefits(Clasen et al., 2014; Prüss-Ustün et al., 2014; Wolf et al., 2014). In light of challenges in diarrhoeal disease epidemiology and WASH impact assessments, focussing on how to best optimize POU interventions is an achievable and appropriate priority for current research (Clasen, 2015, 2009), and can be seen as improving the conditions of ideal exposure to POU. Clasen notes that for a given POU product to achieve impact, it must meet three key requirements: to adequately remove pathogens from drinking-water in "real-world" settings (i.e effectiveness), to be correctly and consistently used (i.e adherence, or compliance), and to be affordable and available to target populations (i.e access) (Clasen, 2015). Access is contingent on supply chain, policy level support to bring POU to scale including private sector support, as well as national and international support. Access arguably requires more of a technical solution, as it is based on a combination of market development, as well as policy-level support. The other two elements identified by Clasen (2015) relate to accurately measuring how well a given POU method performs as it is intended to, and just as critically, achieves the correct and consistent usage required of target populations. Adherence also requires significant behaviour change, and understanding the wide range of associated environmental, psychological, social, and other factors may also be critical(Fiebelkorn et al., 2012). The remainder of this section, and the results presented in this thesis focus on measurements of effectiveness, adherence, and exploring factors correlated to adherence.

2.2.1 POU Effectiveness

Effectiveness vs Efficacy

To investigate how well a given POU product treats drinking-water, it must demonstrate adequate disinfection in controlled settings where contamination can be carefully quantified, as well as produce safe, acceptable drinking water in real world settings. Effectiveness can be defined as: "[t]he extent to which a specific intervention, when used under ordinary circumstances, does what it is intended to do", to be distinguished from "efficacy": "[t]he extent to which an intervention produces a beneficial result under ideal conditions"(Cochrane, 2015). Whereas most laboratory trials are efficacy studies, field trials can be both efficacy or effectiveness assessments, and what constitutes one or the other can be subject to debate (Glasgow et al., 2003). Glasgow and colleagues argue that the vast majority of field studies in public health (particularly prevention and health promotion studies) are efficacy studies, in that they are conducted under "optimum conditions", including carefully selected (often homogenous) populations, complex activities, high follow-up, and expert implementers (ibid). The term "effectiveness" is used in different ways in POU studies, most commonly referring to either health impact effectiveness (e.g the reduction of diarrhoeal diseases), or to improving water quality (e.g the absence of indicator bacteria). In contrast to low adherence, which is a well-cited limitation to POUs' health impact (Clasen et al., 2007; Wolf et al., 2014), the water treatment effectiveness of major POU methods is often considered to be well-established through efficacy assessments and trials (Clasen, 2009; Waddington et al., 2009; Wolf et al., 2014). However many POU field studies arguably present findings that lie in between effectiveness and efficacy, as noted by Glasgow and colleagues (2003). High follow-up activities and encouragement, as well as short-term studies create a relatively artificial context (Eisenberg et al., 2012; Waddington et al., 2009). In particular, water quality measurements in field settings vary widely in terms of the extent and methods by which they are measured. In light of this, the term "field efficacy" is perhaps more accurate to describe much of the "effectiveness" literature.

Measurement challenges

Measuring POU performance under real-world conditions is complex and challenging, including usage-related factors, *in situ* product performance, and the inherent variability of real water sources, all of which are dynamic factors. POU products can function differently over time and based on maintenance. Filtration can be prone to clogging and breakages, liquid chlorine must be carefully bottled and stored, and solar disinfection bottles must be routinely cleaned (Boisson et al., 2010; Shaheed and Bruce, 2011; WHO, 2002). Microbial water quality changes on an hourly, daily and weekly basis within the same source due to environmental and human factors (Levy et al., 2008). The performance of methods employing chlorine is subject to several factors in source water including turbidity, pH, organic content, and temperature, all of which are spatially and temporally variable (Edzwald, 2011; Levy et al., 2009; WHO, 2011). POU effectiveness measures are also reliant on accurate reporting of treatment. For example, water quality assessments of reportedly treated samples in a field study would be biased towards lower effectiveness if a significant proportion of samples were not actually treated. Individual users are the fundamental operating force for any given POU method, and the primary recipients of the method's outcome – safe and palatable drinking water. To function as "intended" (Cochrane, 2015), POU methods must also include user-related considerations, including aspects such as usability, durability, and aesthetic considerations. A more appropriate and widely encompassing definition of POU effectiveness might thus be "field performance".

POU effectiveness

The POU effectiveness evidence base includes a wide range of measurement methods and definitions, many of which may inadequately represent POU performance under real-world conditions. Several studies test water within only a subsample of their exposed population, and often take a single cross-sectional estimate of water (Clasen et al., 2007). Many studies using chlorine-based POU have used detectable free and/or total chlorine residuals as primary effectiveness measures (Arnold and Colford, 2007; Chiller et al., 2006; Harshfield et al., 2012; Lantagne and Clasen, 2012; Reller et al., 2003), while excluding mention of closely correlated properties of ambient water such as pH, turbidity, and treatment/contact time (McLaughlin et al., 2009). The user-related element to POU water treatment is particularly less well covered, including aspects related to appropriate usage and maintenance, and measures that go beyond physico-chemical water quality characteristics such as aesthetic qualities and usability. Furthermore, a significant proportion of the literature is based on intervention trials that are primarily powered to assess the difference between exposure groups, as opposed to measuring effectiveness within groups and over time (McLaughlin et al., 2009). Several interventions that found significant differences between intervention arms also reported some contamination in the treatment-arm (Brown et al., 2008; Lule et al., 2005; Semenza et al., 1998). If this were related to the POU methods not functioning "as intended" (Cochrane, 2015), it would count as reducing effectiveness, particularly given that even small amounts of exposure to contaminated water can greatly increase the risk of waterborne disease (Brown and Clasen, 2012; Enger et al., 2013; Hunter et al., 2009).

Few studies have directly assessed differences between real-world and controlled settings, though the available evidence suggests significant differences between the two. Two of the most relevant studies in this regard were conducted by McLaughlin and colleagues (2009) and Levy et al (2014), assessing liquid chlorine disinfection in rural Ecuador (Levy et al., 2014; McLaughlin et al., 2009). McLaughlin et al (2009) compared chlorine disinfection in target population homes to controlled laboratory tests on surface water in the United States, while Levy and colleagues (2014) assessed user-treated samples to water that they collected and treated at the same site. Both studies found real-world usage to be significantly less efficacious than assessments conducted by researchers (Levy et al., 2014; McLaughlin et al., 2009). Furthermore, Pickering and colleagues (2015) assessed the field performance of a passive chlorinator in Bangladesh, where their "real-world" longitudinal observations indicated lower effectiveness and challenges than expected from earlier, more controlled conditions (Pickering et al., 2015).

Moving forward

International-level guidance on POU products is still in its early stages, and there are as yet no specific guidelines for measuring POU performance in field settings. The WHO recently initiated a POU evaluation scheme (WHO, 2015), and published a guideline on POU Monitoring and Evaluation (WHO, 2012), though the former focuses on laboratory efficacy, and the latter on measuring adherence. Furthermore, these are non-binding normative guidelines. A wide and growing range of POU products are available (WHO, 2015, 2002), developed and produced by a combination of private sector companies, NGOs, and multilateral agencies in different countries (WHO, 2007). POU products are likely to demonstrate a wide range of performance qualities and to have followed a wide selection of national-level and industry-level standards across the markets and regions in which they are available. The International Scheme to Evaluate HWTS was recently launched to address this variability and provide a centralized hub to evaluate POU products, though it also focuses largely on efficacy(WHO, 2015). Nevertheless, several recommendations for field evaluations emerge from a review of these documents, as well as the wider POU literature. Key recommendations include using high quality microbial and physico-chemical indicators, covering as much of a target population as possible and employing longitudinal assessments to account for the considerable variability in water quality and adherence over time (Eisenberg et al., 2012; Levy et al., 2014; McLaughlin et al., 2009; WHO, 2012). Other suggestions are to include information on key covariates related to water quality measurements, such as pH for chlorine-based methodologies, conducting studies in more "natural" usage settings, and including qualitative findings focusing on user-experiences (Arnold and Colford, 2007; Fiebelkorn et al., 2012; Levy et al., 2014; Luby et al., 2008).

POU effectiveness can thus be measured using a wide range of metrics, and collected in many different ways. POU studies need to carefully ensure that the methodologies employed work as intended, demonstrating high efficacy in controlled settings and effectiveness in real usage situations. Household-level behaviour and the number of water sources associated with HWT could lead to considerable differences in effectiveness under real usage conditions. POU effectiveness goes beyond the efficacious disinfection of water, and must also lend itself to being performed properly, and providing water that is palatable as well as safe. "Field performance" may be a more accurate and widely encompassing term than "effectiveness" in the field of POU, and could be defined as: water treatment performance in real world settings by a target population, leading to the provision of safe and palatable water from the point-of-treatment to the point-of-consumption.

2.2.2 POU Adherence

"increasing the supply of HWTS products may be a necessary but not sufficient condition to secure the benefits of household water treatment…unlike vaccines and certain other interventions, water treatment in the home requires householders to embrace and routinely use the intervention in order to provide protection" (Clasen et al. 2009).

The need for high adherence

The health benefits of improved water-quality interventions are delivered through the sustained avoidance of contaminated water, based on interventions successfully breaking the water-related chain of disease transmission (Cairncross and Valdmanis, 2006). POU "compliance", or "adherence" has been defined as the correct and consistent adoption of a given method (Clasen, 2009), or the proportion of treated water out of an individual's total water consumption (Brown and Clasen, 2012; Enger et al., 2013). Adherence measures have several applications, including as primary outcomes to explore behaviour change (Mosler et al., 2010), POU product preferences (Luoto et al., 2011), or as covariates for health outcome studies(Brown et al., 2008). However, measuring POU adherence can be challenging, particularly given the need to follow up on individual- or household-level usage and the fact that water is usually consumed all day, from different sources, and in various settings (Clasen, 2015). Improving reporting on adherence has been widely cited as one of the key needs to improve estimates of POU health impact and sustainability, and as a potential explanation for the variability observed in health impact (Arnold and Colford, 2007; Clasen et al., 2007; Eisenberg et al., 2012; Waddington et al., 2009; Wolf et al., 2014).

A number of studies have explored the relationship between POU adherence and health outcomes using Quantitative Microbial Risk Assessment (QMRA), modelling probabilities of infection based on dose-response findings in reference pathogens(Brown and Clasen, 2012; Enger et al., 2013; Hunter et al., 2009). Hunter and colleagues (2009) examined the risk of infection to three indicator pathogens in the event of interruptions to piped water supplies and subsequent reversions to raw water consumption. Their results suggested that nearly all of the annual health gains from piped water were lost from only a few days of raw water consumption, and that the risk was highest in young children (Hunter et al., 2009). The main role of high adherence was found to be in preventing exposure to particular periods where water was of higher risk, as opposed to a constant baseline risk (Brown and Clasen, 2012; Hunter et al., 2009). Brown and Clasen (2012) and Enger and colleagues (2012) examined associations between the consumption of low quality water and disability-adjusted life years (DALYs). Supporting Hunter et al, both studies also found that even a slight reduction from perfect adherence could lead to drastic increases in risk (Brown and Clasen, 2012; Enger et al., 2013). Brown and Clasen (2012) found that as much as 96% of predicted health gains were lost from a modest decrease in adherence from 100 – 90% (Figure 2.2). In the event of imperfect adherence, higher POU efficacy (measured as log reduction values – LRVs – of indicator organisms), were only associated with marginal health improvements. Indeed, Enger and colleagues also observed diminishing health returns at higher LRVs, below a certain threshold of adherence (Enger et al., 2013). Thus POU interventions likely need to result in high fidelity consumption to deliver health benefits, including all sources of water consumed within and outside the household.

Measurement challenges

Despite adherence being critical to health impact, relevant data is collected with varying definitions, degrees of accuracy, and often missing in much of the evidence base (Waddington et al., 2009). It is very challenging to directly and objectively assess adherence, given the individual household-level practice needed, the number of possible sources for water consumption, and the fact that treatment needs to be sustained for as long as the method is expected to be used.

There are as yet no standard, widely used definitions of adherence, though efforts are being made to make the practice more common. Critically, the term could refer to adherence to the intervention, or to all water consumed. While Clasen (2009) refers to the need for correct and consistent usage of the *intervention*, studies examining health risk require a wider definition focusing on all water consumed (Brown and Clasen, 2012; Enger et al., 2013; Hunter et al., 2009). The latter is more useful to health impact assessments, though more challenging given the need to collect data on all sources of water consumed. The WHO recently published a guideline for monitoring and evaluating POU interventions (WHO, 2012) in an effort to help consolidate and improve the quality of the evidence base. Geared towards simple measurements for field investigations, the majority of factors related to consistent usage are self-reported. However, the report also notes the value of longitudinal measurements, recognizes the need to ideally combine self-reported measures with objective outcomes and to measure correct and consistent usage. Hulland and colleagues (2015) recently published a systematic review of determinants of adoption to WASH interventions, and included their definition of sustained use "the continued practice of a WASH behaviour and/or continued use of a WASH technology at least six months after the end of a project period"(Hulland et al., 2015). This has yet to be used by other studies, however.

A wide range of measures and analytic methods are employed, with varying degrees of accuracy, no common consensus as to their strengths and limitations, nor a set standard of usage (Clasen, 2009; Schmidt et al., 2011). A review of 30 POU studies found that 7 did not report adherence, 9 only measured it by occasional observation, and none did so as a direct measure (Clasen et al., 2007). A great number of studies focus on non-objective indicators, such as intention-to-treat analysis (Jain et al., 2010; Mengistie et al., 2013), and self-reported measures (Inauen et al., 2013; Lilje et al., 2015; Stocker and Mosler, 2015), all of which have been found to be considerably prone to bias, diverging significantly from more objective assessments (Arnold et al., 2009; Colindres et al., 2007; Moser et al., 2005; Olembo et al., 2004; Rosa, 2012). Self-reported identification as being "regular" users may also differ from observed findings because the concept of regular use may not be considered to mean daily and exclusive use (Wood et al., 2012). Several studies have found that POU is practiced when households report having the time (Quick et al., 2002; Reller et al., 2003), or when it is most needed, such as in a particular season (Olembo et al., 2004).

Furthermore, many of the studies that include observed and objective adherence data do so in a limited manner. Water quality is often measured as single sample point-estimates (Albert et al., 2010; Colindres et al., 2007; Harshfield et al., 2012; Lantagne and Clasen, 2012; Olembo et al., 2004), which do not capture the wide variability of microbial water quality measures over time(Levy et al., 2009). Though adherence can be dynamic over time, few studies collect usage data in a longitudinal manner. Albert et al (2010) investigated preferences and adherence to three POU products in Kenya over six months including bimonthly measurements, finding the probability of treated water to drop from 60% to 40% within the first month (Albert et al., 2010). This may also be important to account for any changes in bias over time; for example, Ruel and Arimand (2002) suggest that respondent bias may decrease with successive observations. Furthermore, few studies report on whether households supplement their treated water with untreated sources, though this may be commonly practiced in many settings (Bustamante et al., 2004; Rosa et al., 2014; Shaheed et al., 2014a). Moreover, the majority of POU interventions are at the household level, not taking other sources of drinking-water such as schools, workplaces, or hospitals into consideration (WHO, 2014a).

The evidence

A growing body of evidence indicates that adherence can often be very low, and decrease over time. Reviews by Arnold and Colford (2007), Clasen and colleagues (2007), Hunter (2009), and Waddington and colleagues (2009) found overall decreases in the health impact of longer duration studies (Arnold and Colford, 2007; Clasen et al., 2007; Hunter, 2009; Waddington et al., 2009). One of the main reasons suggested for the decrease in impact over time was "discontinuance" of the

POU methods as perceived costs of adherence outweighed benefits (Waddington et al., 2009), interest decreased, and user-fatigue rose (Arnold and Colford, 2007). Table 2.2, adapted from Rosa (2012) presents a non-exhaustive, non-systematic list of publications where intervention sites were revisited to assess sustained usage. It indicates an extremely wide range of adherence, from 0 to over 90%, while also underlining the range of different measures employed.

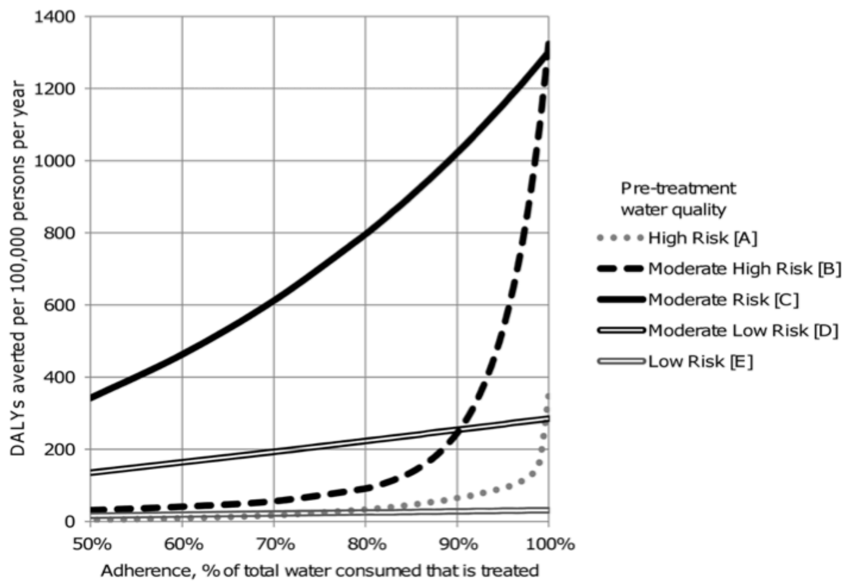
In light of the challenges in adherence and long-term health impact, Schmidt and Cairncross (2009) suggested that the ideal setting for POU methods might be short-term implementation contexts, such as during emergencies (Schmidt and Cairncross, 2009). However, here too, the modest available evidence suggests high variability, and often very low adherence (Brown et al., 2012; Colindres et al., 2007; Doocy and Burnham, 2006; Lantagne and Clasen, 2012). Doocy and Burnham (2006) investigation of a refugee camp in Liberia recorded the greatest adherence, finding over 95% adherence over a 12 week period. Colindres and colleagues (2007) investigated CDP use among 100 flood-affected households a few weeks after relief operations, finding only 22% with reportedly-treated water on the premises, of which only 45% were found with detectable chlorine. Lantagne and Clasen (2012) assessed chlorination programmes conducted during four acute emergencies in Nepal, Indonesia, Kenya, and Haiti. Less than 22% of the target populations in Nepal, Kenya and Indonesia were found to have detectable improved water. Furthermore, Atuyambe et al (2011) observed the concurrent consumption of untreated water in refugee camps in Uganda, largely due to taste and convenience, highlighting that such considerations could still affect usage in high risk settings.

A number of studies have also reported considerably high adherence (Chiller et al., 2006; Parker et al., 2006; Thevos et al., 2000). Thevos and colleagues (2000) observed chlorine residuals in roughly 71 - 95% of their target population in Zambia over 8 weeks, following motivational interviewing. Parker et al (2006) found between 68-71% of their target population in Kenya to have free chlorine residuals during unannounced visits, 2 weeks and 1 year after intervention. Chiller et al (2006) found over 85% of study participants to have detectable chlorine in Guatemala over a 13 week period. However, high adherence studies are in a minority within the limited available data, and a number of weaknesses can be identified in some. Parker et al (2006) only assessed adherence in a non-randomized selection of visitors to a health clinic, including less than 100 households after 2 weeks, and only 51 after a year. Furthermore, three unannounced visits conducted by Chiller and colleagues (2006) over the course of the same study indicated considerably lower adherence rates, dropping over time from 66 to 44%.

A critical gap

High adherence is critical to optimizing POU interventions, yet not reported with a common definition, sufficient frequency, nor quality. The clearest conclusion that can be drawn from the current POU adherence evidence base is that it is highly variable, poorly estimated, and often challenging for target populations. Definitions and measurement guidance are still in early stages of development. Further research could investigate best practices for assessing adherence, and help consolidate methods to lead to more comparable findings across studies. The consistent inclusion of adherence measures could greatly improve the POU evidence base, helping assess health impact, providing an objective and critical component to compare various interventions and POU methods with, and ultimately lead to a better understanding of POU water treatment's scope and potential for scale.

Figure 2 2 DALY's averted from different levels of adherence and water risk *



*From (Brown and Clasen, 2012)

Table 2 2: Non-systematic summary of studies reporting on adherence post-intervention*:

*Adapted from (Rosa, 2012

Author and year	Location	POU technology	Time after intervention	Comment
(Brown, Sobsey et al. 2007)	Cambodia	Ceramic filter	1- 4 years	Only 31% of the follow-up households were using the filter and use was strongly associated with time since installation-59% of HH had them installed less than 36 months ago.
(Clasen, Brown et al. 2006)	Bolivia	Ceramic water filter	4 months	67% were being used regularly and correctly.
(Aiken, Stauber et al. 2011)	Dominican Republic	Biosand Filter Product given as part of a RCT or just distributed to other communities	1 year	90% of the filters were still in use.
(Iijima, Oundo et al. 2001)	Kenya	Pasteurisation,	4 yr	Only 30% continued to pasteurise their water.
(Rainey and Harding 2005)	Nepal	SODIS	3-4 months	Only 9% routinely practised SODIS.
(Moser, Heri et al. 2005)	Bolivia	SODIS Different promotion strategies employed in 8 villages	2 months – 5 years	Reported current SODIS use ranged from 2.5% to 88.8% among the eight villages. However, availability of treated water at time of visit ranged from 0% to 72%.
(Luby, Mendoza et al. 2008)	Guatemala	Flocculant- disinfection Product given as part of a RCT. At the end of the study an intensive marketing campaign was rolled out	6 months	Of the 462 surveyed households, just 14% reported using the flocculant-disinfectant in the preceding week, while only 5% met the criteria for active repeat use and only 1.5% had detectable chlorine in their drinking water.
(Colindres, Jain et al. 2007)	Haiti	Flocculant- disinfection Distribution of HWT among affected population after flooding	2 weeks	Only 22% of households that received the HWT product reported having treated water at the time of the visit. (of them less than 50% (i.e 9% overall) had free chlorine equal or greater than 0.2

Author and year	Location	POU technology	Time after intervention	Comment
(Ram, Kelsey et al. 2007)	Madagascar	Chlorine Community-based sales agents disseminated SWS	1 year	73% reported chlorine use but only 54% of these had detectable chlorine.
(Mong, Kaiser et al. 2001)	Madagascar	Chlorine Relief kits containing SWS were distributed among cyclone affected population	5 months	43% were observed using the improved storage container for drinking water storage and 65% indicated current chlorine use. Free chlorine residuals greater than 0.2 mg/L were found in almost half of the water samples tested.
(Makutsa, Nzaku et al. 2001)	Kenya	Chlorine Distributed SWS in combination with a social marketing approach	6 months	Only 33.5% of households had detectable free chlorine in stored water and only 18.5% were using the modified safe storage containers.
(Colindres, Mermin et al. 2008)	Uganda	Chorine Basic care package including HWT given to people attending clinic	3-7 months	65% reported currently treating their drinking water, but only 36% had measurable chlorine residuals.
(Sheth, Russo et al. 2010; Wood, Foster et al. 2012)	Malawi	Chlorine Free hygiene kits that included WaterGuard distributed at antenatal clinics	1 year and 3 years	61% and 28% confirmed used among receivers of the hygiene kit including WaterGuard.
(Parker, Stephenson et al. 2006)	Kenya	Chorine Nurse provide information on HWT that attend clinic	1 year and 3 years	Free chlorine residuals were present in stored water of 68% of clients that had received information on HWT after attending the clinic. However, it should be noted that no baseline data on chlorine levels in the water was obtained.
(Arnold, Arana et al. 2009)	Guatemala	Boiling, Chlorine and SODIS. Community-based health promoters visited participant household and promote HWT and handwashing	6 months	The proportion of households reporting HWT dropped from 70% at the end of the intervention to 37% six months later.
Brown and Sobsey 2012	Cambodia	Consistency of boiling over 6 months in Cambodia.	6 months	despite >90% reported regular boiling, only 31% of households had boiled water on premises during follow up visits, 56% of boiled samples had E.coli (27% had 10 or more CFU/100ml)

2.2.3 Determinants of POU adherence

"Behavioural mechanisms, the beliefs, values and experiences of the treatment population and the socio-economic environment are important determinants of the adoption and sustainability of interventions"(Waddington et al., 2009).

Keep a watch…on the faults of the patients, which often make them lie about the taking of things prescribed. For through not taking disagreeable drinks, purgative or other, they sometimes die. Hippocrates, *Decorum (Brown and Bussell, 2011).*

The challenge in measuring and understanding adherence

Together with better measurements of adherence, understanding contextual and behavioural factors interacting with and influencing adherence may be critical to improving correct and consistent use (Fiebelkorn et al., 2012). High adherence to POU methods requires considerable behaviour change, and may be challenging for target populations to implement. Characteristics of water treated by such methods may require significant adaptation to render acceptable and maintain user-consistency. POU interventions may often be less intuitive, more complicated, and different to traditional water treatment and storage practices, particularly for the most vulnerable demographic groups (Clasen, 2015). The behaviour change required needs be conducted consistently, usually include maintenance of the methods involved (e.g backwashing water filters, cleaning storage containers), and restrict the consumption of untreated water (Rosa et al., 2014). Understanding how to change human behaviour has been described as the "holy grail" of health promoters, psychologists, marketers, and policy makers (Aunger and Curtis, 2010). There is no consensus on a unifying theory of behaviour change, however, and a wide range of competing frameworks and models exist, often specific to their particular fields of interest (Aunger and Curtis, 2010). It is a relatively nascent field within WASH and POU studies, and there is considerable scope for adding to the evidence base, as well as consolidating lessons and theoretical frameworks.

Adherence in the wider public health literature

Adherence is a central issue in public health, affecting most branches within the field, particularly those involving interventions and any significant change in target population behaviour. The WHO defines adherence as "the extent to which a person's behaviour - taking medication, following a diet, and/or executing lifestyle changes - corresponds with agreed recommendations from a health care provider"(WHO, 2003). The terms *adherence* and *compliance* are often used interchangeably, though "adherence" is often seen to be less paternalistic than "compliance"(Dulmen et al., 2007; Rosenbaum and Shrank, 2013; WHO, 2003). It is an extremely complex, dynamic, and multifaceted issue, requiring several considerations spanning the consumer, provider, health systems and broader socio-economic and political contexts (Munro et al., 2007). The core of adherence literature focuses on adherence to medicine, often in the context of clinical interventions, though it also extends into most branches of public health, from condom use and safe sex practices(MacPhail and Campbell, 2001; Sheeran et al., 1999), to helmet use and road traffic safety(Lin and Kraus, 2009), to hygiene practices such as handwashing (Pittet, 2001). While findings are often specific to the context and health outcome being investigated, low adherence may also be affected by more general issues of behaviour change, which are as yet not properly understood.

As illustrated in Brown and Bussell's (2011) simple chain: "Treatment ➔ Adherence ➔ Outcomes", adherence is often a central component to an intervention achieving impact. A meta analysis by Dimatteo et al (2002)found a 26% difference in health outcomes between high and low adherence studies, and a 2003 WHO report suggests that improving adherence alone may have a greater impact than improving the effectiveness of treatment, in many cases(WHO, 2003). However, adherence is often remarkably low. Between 30-50% of prescribed medication, depending on the disease and health care system is not taken as directed(Brown and Bussell, 2011). Even when provided free of charge, adherence may be as low as 40%(Cutler and Everett, 2010). It is estimated that between one- to two-thirds of medication related complications in the US are due to non-adherence, amounting to between 100 to 290 $ billion USD in avoidable hospitalization costs(Osterberg and Blaschke, 2005; Rosenbaum and Shrank, 2013). Though adherence is generally lowest in patients with chronic illnesses and greatest in those with acute illnesses (Brown and Bussell, 2011; Dulmen et al., 2007; Haynes et al., 2008), a study in Germany observed similar prevalence rates - of at least 33% - across the general population, suggesting that non-adherence is a wider and more inherent issue than the specific context it is being examined in (Glombiewski et al., 2012).

Several factors can affect adherence studies, from measurement challenges to the theoretical suppositions informing analysis and collection of potential determinants. As discussed in Section 2.2.2, adherence can be extremely challenging to measure, with the simplest approaches such as intention-to-treat analysis or self-reported adherence being subject to considerable bias, and more complex objective measurements using pill counts or biochemical measurements being cost intensive and introducing bias of their own(Brown and Bussell, 2011). Furthermore, the central role of human behaviour to intervention adherence creates considerable scope for incorporating lessons from the wider field of behaviour change in psychology and sociology. However, progress on this front may still be limited, and"[i]t is as yet unclear whether some theoretical constructs might be more convincing than others in explaining and improving non-adherence "(Dulmen et al., 2007). While there is a substantial body of literature examining determinants of adherence and behavioural interventions, it has been found that at least half of all adherence-related interventions seem to fail (Haynes et al., 2008). Other reviews find that non-adherence rates have remained unchanged despite several decades of studies, citing a need to improve on the quality of behaviour change research, with a greater emphasis on theoretical constructs amongst other factors (Dulmen et al., 2007; Rosenbaum and Shrank, 2013; Vermeire et al., 2001). Together with more systematic and higher quality behaviour change studies, studies also suggested improved monitoring using technological solutions (Beni, 2011), or financial incentives (DeFulio and Silverman, 2012).

The challenge of adherence may be a deeply rooted one. A "one size fits all" solution is unlikely given the multifactorial nature of adherence and the many contexts to which it may be applied, and it would appear that all relevant fields of public health still need to make significant advances in adherence studies. Adherence-related issues may be even more complex for cases involving complex behavioural changes than taking medication, and in less controlled settings. Environmental health interventions such as hand washing with soap, or treating water in rural communities are good examples of such more complex settings.

Overview of behavioural theories underlying the WASH literature

A growing body of evidence suggests that public health interventions requiring behaviour change are more effective when grounded or analysed within a theoretical framework (Glanz and Bishop, 2010). The majority of behaviour change models in public health have been influenced by a few seminal general theories of behaviour change and health (Ajzen and Fishbein, 1980; Bandura, 1986; Prochaska and Velicer, 1997; Rosenstock et al., 1988), and further developed within specific fields. It is a relatively new and growing area in WASH (Fiebelkorn et al., 2012; Hulland et al., 2015). Kincaid and Figueroa (2010), and Aunger and Curtis (Aunger and Curtis, 2010) outline key general theories that inform many of the more WASH-specific findings. Aunger and Curtis (Aunger and Curtis, 2010) identify four main categories of frameworks: Stage, Psychological, Environmental, and Process approaches.

Stage approaches indicate the various stages through which an individual must go through to perform a behaviour (e.g contemplation; preparation; action; maintenance; termination(Prochaska and Velicer, 1997)). Stage models include some of the most cited and influential frameworks, including the Diffusion of Innovations theory (Rogers, 1962) and the Transtheoretical, or Stages of Change Model(Prochaska and Velicer, 1997). However, they have also been criticized for appearing overly linear, time-bound, and the fact that individuals do not necessarily move successively from one stage to the other, and can often revert back to a prior "stage"(Figueroa and Kincaid, 2010). They also fail to include the social, physical, historical, and cultural context in which the behaviour change is intended(Aunger and Curtis, 2010; Figueroa and Kincaid, 2010).

Aunger and Curtis found that the vast majority of behaviour change theories fell within the Psychological approach, including several of the major theories such as Ajzen and Fishbein's (1980) Theory of Planned Behaviour, and Rosenstock, Hochbaum and colleagues' (1988)Health Belief Model. These theories highlight the importance of beliefs, attitudes, intentions, norms, and self-efficacy on behaviour. While useful for their value in predictive assessments (Albarracín et al., 2001), they have been criticized for being too grounded in cognitive psychology, focussing on rational decision making processes(Aunger and Curtis, 2010; Dreibelbis et al., 2013). Such approaches disregard other aspects of human behaviour and motivations such as emotional and irrational drivers (Bandura, 1986; Kahneman, 2011), as well as other "unconscious or implicit mental processes" involved in behaviour(Aunger and Curtis, 2010). Habit formation, or "learned automatisms" are increasingly being seen as an important component to health behaviours related to hygiene, eating, or exercise(Aunger and Curtis, 2015).

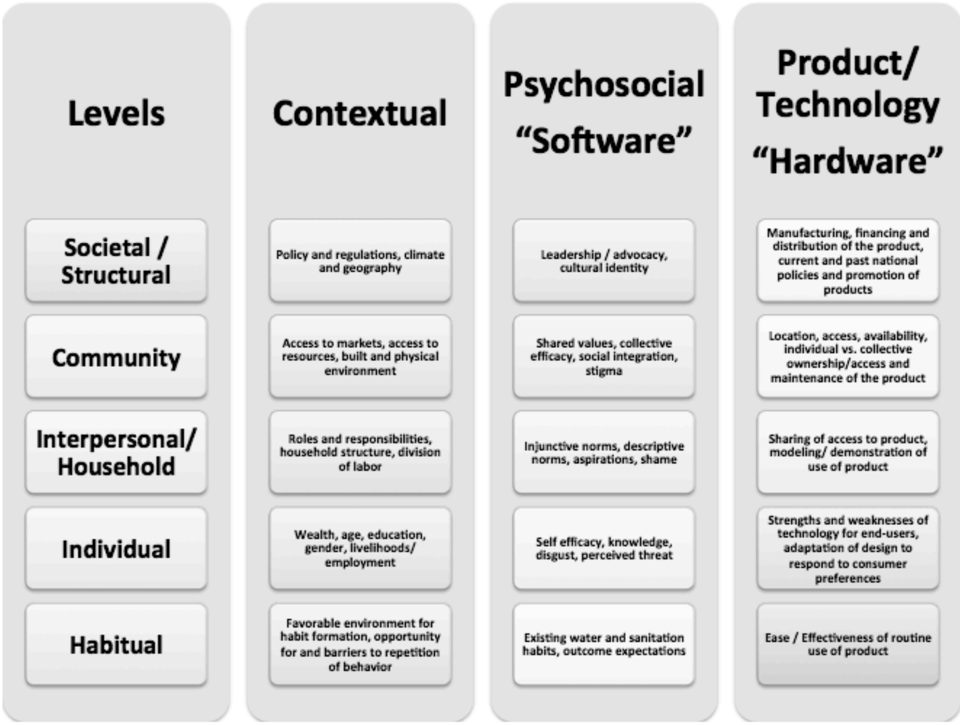
Environmental approaches assess the role of the context, including the physical and social environment that behaviours take place in, and though little covered in most of the major and more traditional theories, are being given increasing importance in behaviour change science (Glanz and Bishop, 2010). Such approaches typically consider multiple spheres or "levels" of influence from the individual, to the household, to the communal, and finally up to the national and policy level (Bandura, 1986; Glanz and Bishop, 2010). Process approaches focus on guiding implementation of behaviour change programmes, and while Aunger and Curtis note their potentially considerable value to practitioners, they are also relatively rare and mainly used in social marketing (Aunger and Curtis, 2010; Kotler and Zaltman, 1971).

Behaviour change in the WASH and POU literature

Three recent systematic reviews highlight key findings and gaps in the WASH and POU behaviour change literature (Dreibelbis et al., 2013; Fiebelkorn et al., 2012; Hulland et al., 2015). Dreibelbis and colleagues' (2013) conducted the first systematic review focusing on WASH-specific theoretical models. Their findings supported previous reviews (Aunger and Curtis, 2010; Fiebelkorn et al., 2012), noting that the majority of factors centred around individual-level determinants often rooted within psychological concepts, that the roles played by the primary intervention hardware, environmental factors, and multiple levels of influence were under-represented. Their review was used to develop the Integrated Behavioural Model for Water, Sanitation, and Hygiene (IBM-WASH) (Dreibelbis et al., 2013). The IBM-WASH model aims to provide a more balanced view of behavioural determinants, in an overall ecological framework. It can be easily adapted to different studies' foci, and does not require stringent adherence to specific constructs (Mosler, 2012), and has been used successfully in recent studies (Hulland et al., 2013; Najnin et al., 2015). It is well suited for exploratory analysis, qualitative research, and informing implementation. Furthermore, the weight given to technological factors makes it particularly appropriate for POU interventions.

The model focuses on three key "dimensions", related to "psychosocial", "contextual", and "technological" considerations. "Contextual" factors represent background characteristics, often those that cannot be influenced by an intervention. These include characteristics of the individual, the environment, or the setting, including socioeconomic level, media exposure, access to water, and population mobility. "Psychosocial" factors can usually be influenced by an intervention, and include many of the traditional foci of behaviour change interventions, such as the factor blocks in the RANAS model (Mosler, 2012), psychological approaches outlined by Curtis et al(2009), and intermediate outcomes identified by Figueroa and Kincaid(2010). Key factors include disgust, attitude, social norms/desirability, nurture/caretaking and motherhood, behaviour change knowledge, social integration, perceived risk of illness, and self-efficacy. "Technological" factors relate to the main hardware in WASH activities such as soap, latrines, or water treatment products. Factors related to this dimension include the location of technology, ease of use and convenience, design, and valuations. Each of these three dimensions operates on five aggregate levels: "societal", "communal", "household", "individual", and "habitual".

Figure 2 3: Schematic of the IBM-WASH model



"IBM-WASH Integrated Behavioural Model for Water, Sanitation and Hygiene", Supplementary material, additional file 1) http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4231350/

Most recently, the IBM-WASH framework was used by Hulland and colleagues (2015), who published the first systematic assessment of factors related to adherence across different WASH interventions (Hulland et al., 2015). They identified several factors that are also found in POU-specific studies, including: interpersonal factors and social norms relating to family, community members, and implementing agents (Schlanger, 2012; Wood et al., 2012); the perceived need to engage in the behaviour and the perceived risk related to the behaviour not being conducted, often related to seasonal and purposive considerations (Doria et al., 2009; Inauen et al., 2013; Lilje et al., 2015; Olembo et al., 2004; Wood et al., 2012); self-efficacy, or confidence in the ability to perform the behaviour change(Mosler et al., 2010); cost and durability of the technology used (Wood et al., 2012); socioeconomic and demographic considerations (Freeman et al., 2012; Komarulzaman et al., 2014; Sheth et al., 2010), and pre-existing habits or experiences related to the behaviour (Lantagne and Clasen, 2012).

Fiebelkorn and colleagues' (2012) systematic review of the POU-specific behaviour change literature focused on a critique of the evidence base, underlining the low quantity and quality of available findings. Less than two per cent of the 1551 published papers identified by their search addressed behavioural factors affecting POU adoption. Several studies included too little data to be reproducible, or to conclusively link a particular behaviour to POU usage. They noted the bias in self-reported outcome measures (Lilje et al., 2015; Mosler et al., 2010), and the weakness of proxy behavioural outcomes (e.g sales to monitor actual usage) (Harshfield et al., 2012), suggesting that studies employ longitudinal, repeat measurements using more objective adherence outcomes. They underlined the benefit in evaluating findings from a behavioural perspective, and using one or more theories to inform the design and analysis of findings (Fiebelkorn et al., 2012). Finally, they also noted the value of using formative research and qualitative methods in addition to survey findings to provide a more complete picture of behaviour change.

A better understanding of behavioural factors may help understand how to best inform POU design and implementation to achieve the greatest impact and effective scale (Clasen, 2009; Fiebelkorn et al., 2012; Waddington et al., 2009). There is a need for more, and better quality assessments, helping validate previous findings, and inform potential new avenues to explore. Methodological considerations for intervention studies include the use of theoretical frameworks, viewing behaviour change within its wider, contextual settings, and observing multiple-levels of influence and impact. One of the most critical aspects to this field is how findings will translate to interventions, which are arguably the least addressed in the current literature. This includes assessing whether addressing user perceptions is the best manner to improve adherence, or whether it may be best to focus on changing current POU options, as suggested by some reviews (Clasen, 2009; Figueroa and Kincaid, 2010). Further research in this growing field will help address many of these questions, as well as clarify the scope for POU interventions and the best contexts in which to bring them to scale.

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Chapter 3. General Methodology

3.1 STUDY METHODS AND TOOLS

3.1.1 Study design overview

This study was a mixed-methods, longitudinal, repeat-visit crossover trial. It employed a two-period, or AB/BA design where one group received exposure A (e.g Pureit) followed by B (e.g PoW), and the other received B before A. The term "crossover" refers to when participants changed exposure status, and a crossover "period" refers to the time a given exposure lasted (Senn, 2002). The principal unit of measurement was the household, as water treatment is typically a household-level activity. All participating households were randomly and equally divided between exposure to Pureit (A) or PoW (B) for the first one-month crossover period, after which they were allocated to the alternative product for the second month. Households were provided with training on product usage, sufficient sachets for one month, and ancillary supplies to treat and safely store water. Households were visited on an approximately weekly basis (four visits per period), though the specific time and day of visits was unannounced. The crossover was implemented at the end of the fourth visit, when households were given a new batch of sachets to use for the next period.

Overview of tools:

A quantitative survey was administered at each visit, recording observed and self-reported sachet usage, physico-chemical water quality measurements in reportedly treated samples, and select covariates as potential predictors of adherence. The survey was supplemented by a number of pre- and end-of-survey focus group discussions (FGD) and semi-structured interviews (SSIs), to expand on findings related to product feedback as well as determinants and barriers to adherence. All study tools are further detailed in section 3.1.3. Figure 3.1 presents an outline of the implementation design and data collection.

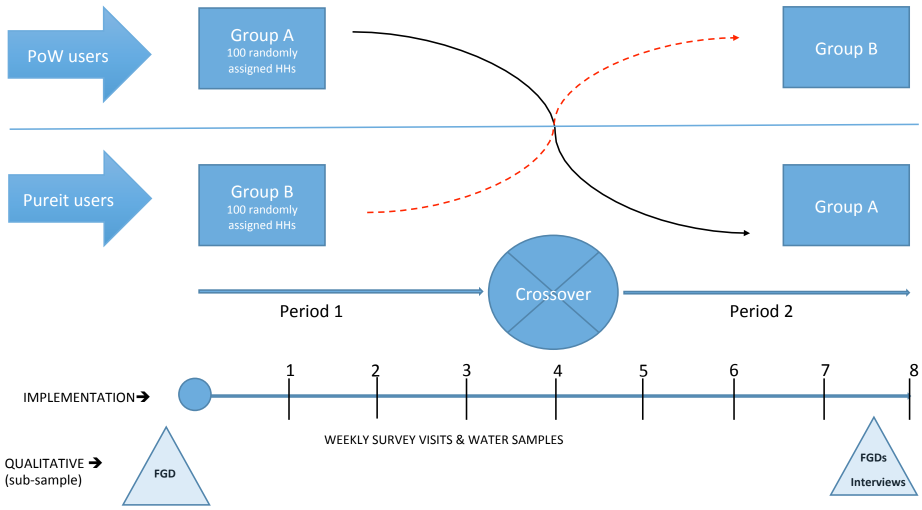
Rationale for design:

- Employing a crossover design allowed a careful assessment of product differences, comparing product usage within the same households as well as between users of each product over any point(s) in the study. Randomized product allocation and the crossover design were expected to minimize potential confounding, and address concerns raised in reviews related to the medium and often low quality of POU study designs (Fewtrell et al., 2005; Waddington et al., 2009). A one-month timeframe was selected to reflect short-term adoption settings, as might be expected in emergencies, and to measure potentially rapid drops in usage, as suggested by certain recent studies (Albert et al., 2010).

- Weekly repeat visits allowed the study to accurately measure adherence and assess any variability over a short timeframe. Repeat visits have also been suggested to be an adequate replacement to structured observations of behaviour, and by being less intrusive, potentially reduce user "reactivity" and other potential sources of bias (Ruel and Arimond, 2002). Employing unannounced visits also helped reduce potential bias related to usage findings.
- A washout phase – where households would not be exposed to either product before the second crossover period (Senn, 2002) – was not considered necessary for this study. Unlike studies such as drug trials where physiological effects could remain after the end of the first period, the usage of two similar water treatment products was considered unlikely to require a washout period. Any "carry over effects", or differences based on whether households were in the AB or BA group were expected to be due to differences in user perceptions based on their experience using the first product (e.g learning how to use the first product may affect usage of the second) though this effect could not be predicted.
- Mixed-methods studies have been widely noted to be valuable in understanding behaviour change and adherence-related factors (Fiebelkorn et al., 2012; Waddington et al., 2009).
- Collecting water samples during unannounced visits gave the study an objective outcome of usage – treated water on the premises. Testing samples for post-treatment pH as well as free and total chlorine residuals provided data to assess and compare product performance. Free chlorine provided a measure of safety (based on the amount of free residual chlorine available (WHO DWQ)), and total chlorine was used to assess the presence of any chlorine whatsoever, and thus, a validation of user-reported treatment.
- Used sachet data provided an objective, quantifiable outcome for adherence measurement. Observed sachet usage was recorded every week, including used, unused, and missing sachets. Weekly sachet usage could be used to extrapolate daily usage since the previous visit, and given that each sachet treated a set quantity of water, calculate consumption per household and per capita. Used sachet counts allowed the study to assess usage throughout the study as opposed to just during

visits, as was the case with water samples. Stated sachet usage was collected in order to compare with observed measures.

Figure 3 1 : Overview of study design



3.1.2 Sample size

This study was powered to account for group differences between Pureit (A) and PoW (B) usage in an AB/BA crossover design with repeat measures. A recent overview of crossover study designs and analysis methods found generally low reporting of sample size calculations, and a range of methods employed in those that were reported (Mills et al., 2009). Calculations need to account for the crossover element as well as how data is being collected (e.g whether it is taken at one or more time points). No definitive method could be found for sample size calculations in repeat-visit crossover studies, and an approach was devised based on the best available evidence (Mills et al., 2009; Rietbergen and Moerbeek, 2011; Senn, 2002).

The sample size was calculated in two stages, using an approach for two-arm longitudinal trials that was then modified to account for crossover effects. The principle outcome of this study was PoW/Pureit sachet usage. However, for the purposes of this estimation, usage was defined as the presence or absence of detectable total chlorine in water samples collected at a given visit. This was considered to be a more objective outcome than setting a given number of observed or reported used sachets per week, particularly in light of the variability seen in the CDP adherence evidence base (outlined at the bottom of this section). The primary unit of measurement was the household, the level at which POU water treatment is chiefly conducted.

A literature review was conducted to inform the detectable difference to assess between the two products as well as the overall level of adherence to expect. Among the most relevant studies was a two-month longitudinal POU usage trial by Albert and colleagues (2010) in Kenya (Albert et al., 2010). Adherence (defined as the fraction of treated water with *E.coli* concentrations <1 colony forming unit/100mL) was highest in the first week of the study (at 60%), and dropped to 40% within the first month (a 33% reduction), where it remained relatively stable through the second month. Albert and colleagues (2010) assessed three products (a filter, liquid chlorine, and a CDP), finding CDP usage to the be lowest (ibid).

The first step to our calculation was based on the methods outlined by Diggle et al (2002), and Leon (2004) to analyse binary outcomes with repeated observations (Diggle et al., 2002; Leon, 2004). Equation 3.1 was used to calculate the required number of participants for a two arm trial over four repeat observations. In light of our study using two flocculant-disinfectants, and in order to remain conservative, an initial adherence level of 50% was set, powered to detect a 20% difference between products, and an intraclass correlation coefficient of 0.1. This calculation yielded 126 households required per arm (252 households in total), observed over four visits per household.

The second step was to bring the crossover design into consideration. Several studies note that crossover designs can substantially increase the statistical efficiency of effects estimates, consequently reducing the required sample size. Though no conclusive estimates of power reduction were identified, it was estimated to be as high as 50% (Donner and Klar, 2000; Rietbergen and Moerbeek, 2011; Turner et al., 2007). For this study, a more conservative reduction estimate of 25% was made to the initial assessment of 126 households per arm, leading to 100 households per exposure arm, and 200 households in each country study. As the primary comparison in a crossover design is within the same unit of measurement (i.e usage in households exposed to PoW and Pureit), the two arms referred to in this calculation actually refer to the different exposures (products) given to the same households at different times (i.e one month each). Our sample size calculation is thus primarily for 100 households to be followed for four repeat measures, and subsequently exposed to the alternative product, as the second “arm”. However, in order to account for order effects, 100 households were exposed to Pureit before PoW (AB), and a further 100 to PoW before Pureit (BA). It is an advantage of this design that different groups of households could also be compared to each other, including: Pureit vs PoW users in crossover period 1 or 2, respectively, and the total sachet usage of all households to Pureit and PoW (both periods). Finally, in order to account for a 10% potential loss to follow-up and issues with data integrity, at least 220 households were recruited in each site .

Equation 3.1: Sample size equation based on Diggle et al. (2002) and Leon (2004) to analyse binary outcomes with repeated observations:

$$m = \frac{(z_{\frac{\alpha}{2}}\sqrt{2\overline{pq}} + z_{\beta}\sqrt{p_A q_A + p_B q_B})^2 (1 + (n-1)\rho)}{nd^2}$$

Where:

$Z_{\alpha/2}$= Z value at α= 0.05

Z_{β}= Z value at (1-β)= 0.8

p_A= response rate for group A

p_B= response rate for group B

q_A= 1-p_A

q_B=1-p_B

p(bar)= (p_A+p_B)2

q (bar)= 1-p(bar)

n= number of observations

ρ= intraclass correlation coefficient

d= smallest meaningful difference to be detected

Variability in the CDP evidence base

Used sachets were not employed in the sample size calculation as the evidence from studies focusing on CDP usage varied widely and did not have sufficiently reported details. A number of studies have assessed CDPs (Chiller et al., 2006; Colindres et al., 2007; Crump et al., 2005; Luby et al., 2008; Reller et al., 2003), and though sachets were counted in all of them, only one reported on longitudinal sachet adherence over time (Chiller et al., 2006). Chiller and colleagues (2006) found weekly household usage to rise steadily from 5 to 10 sachets per week over 13 weeks. On the other hand, Luby and colleagues found average usage to be as high as 21 sachets per week in a 9 month study in Karachi (Luby et al., 2004). Reller and colleagues (2003) conducted a one year study in Guatemala, finding an average of 6 sachets used per household per week. Crump and colleagues 20-week study found over 85% of users to have detectable chlorine during weekly scheduled visits, but only 44% during unannounced visits(Crump et al., 2005).

3.1.3 Data collection tools

3.1.3.1 Quantitative data collection

Overview

The primary data collection tool was a weekly-administered survey including data on sachet usage, water quality of available samples, and select covariates. Sachet usage was collected at every visit, and water quality was tested at every visit where households reported having treated water. Different covariates were collected at different time points, with a small number collected at every visit, some at the end of each phase, and the majority obtained at a single time point. In addition, focus group discussions (FGDs) and semi-structured interviews (SSIs) were conducted within a representative subsample of the study population, mostly towards the end of the study, focusing on probing determinants of adherence and product feedback in more detail.

Survey

The main respondent was the primary caregiver; typically an adult female responsible for the majority of domestic matters including water treatment. Other consenting adults could be included, in their absence. Each questionnaire was divided into nine sections: the first was baseline data including household demographics taken during household recruitment, followed by one section for each of the eight follow-up visits. The primary outcomes, and a select number of key covariates were "repeat questions", collected at every visit. A small number of additional questions were asked at the end of each crossover phase, focussing on product feedback, and the remaining covariates were collected at a single time point, distributed across the final three visits of the study.

Implementation and follow-up visits aimed to influence behaviour change as little as possible, as this study intended to assess usage in settings approximating real-world contexts. Enumerators were encouraged to underline the fact that households were free to use the products as much or as little as they liked, while emphasising the importance of being honest in their feedback. Auxiliary product-related discussions were confined to clarifications of survey questions, and advice on correct product utilization. Enumerators could also engage in general conversation with households about other matters, to maintain an amicable relation that could help foster accurate information gathering.

Repeat questions were identical in both countries, but the order and details of non-repeat questions differed somewhat, particularly as the questionnaires also saw slight changes over the course of the project as greater feedback was gleaned from experience (i.e, a certain question for visit 6 would be altered or added during visit 5 based on the team's findings). Approximately 90% of the two country questionnaires were identical.

Baseline visit: The baseline visit was conducted the same day households consented to participate in the study (see section 3.1.4). This visit included data covering all household members, including age and education, as well as health outcomes, focusing on self-reported diarrheal disease, though the majority of the questionnaire used data at the household-level.

Repeat questions: Initial follow-up visits did not go beyond the repeat questions: feedback on sachet usage and collection of water samples. This was in order to minimize courtesy bias and household time requirements.

- Information on product feedback and self-reported determinants of usage and acceptability was collected at the end of each study phase.
- Health outcome information collected at baseline was also asked at the end of the second crossover period in Zambia, and at the end of both crossover periods in Pakistan.
- At the end of each phase, households conducted "mock" demonstrations of product use, where they enacted all steps in their treatment, including noting waiting times, while not actually treating water in order to save time. Enumerators ranked each step for each product out of three.

Questions asked at a single time-point: The remaining covariates were distributed across the final three visits of the study (visits 6 – 8). Questions were divided in this manner to reduce household interview time, and most covariates were collected towards the end of the study on the premise that households would be more open in their responses after building a rapport with enumerators. It was also expected that greater familiarity with the team would encourage more honest responses, with lower courtesy bias. Repeat visits lasted approximately 15 minutes, while the longer visits in the second crossover period could extend up to 30-35 minutes. Questionnaire answers were coded numerically. Used sachets and water quality metrics were recorded as discrete outcomes, and all covariates were coded, with the majority as categorical outcomes. Questions used in descriptive analysis could have single and multiple answers, and all other questions only had single answer options. Table 3.1 presents an overview of all data collected during the study.

Table 3 1: **Quantitative survey overview**

DATA COLLECTION FREQUENCY	QUESTION CATEGORY	QUESTION SUB-CATEGORY	VARIABLE INFORMATION
WEEKLY REPEAT QUESTIONS	Sachet usage	Observed used and unused sachets ◊ Reported frequency in past week	Continuous
	Usage covariates	Consumption of untreated water ◊ Usage of treated water for other purposes ◊ Household dynamics regarding usage	Categorical
	Water sample collection	Free and total chlorine ◊ pH ◊ turbidity ◊ Number of containers used, their type and maintenance ◊ Method of sample extraction and provision ◊ presence of untreated water **	Continuous & discrete based on detection capability of each method
Data collected at two time points			
- End of each study phase	Product feedback	Product rating ◊ Rating product safety before and after treatment ◊ Positive and negative feedback for each product ◊ Self-reported changes in usage over phase and reasons ◊ Enumerator-graded "mock" demonstrations of product usage (acting and explaining all steps, without waiting the full contact and stirring time) ◊ Willingness to pay for product ◊ trust and willingness to recommend product to others ◊ Product preference (if any) and reasons ◊ Factors making treatment easier or harder over time	Ratings: out of 10 Demonstration : a score. Six elements were assessed, each out of three (maximum points: 18) Willingness to pay: in local currency, converted to USD Remaining questions: categorical
Data collected at two (or three) time-points	Self-reported health outcomes (Asked at baseline and the end of crossover phase 2 in Zambia, and in	Malaria (HH-level) ◊ Skin rashes (HH-level)* ◊ Typhoid (HH-level) ◊ Diarrheal disease 7-day prevalence (collected for each household member)	Categorical

	Pakistan, also asked at the end of phase 1).		
Data collected at one time point			
- Baseline	Socio-demographic data	Household size ◊ Age (all members) ◊ Education level ◊ Demographic groupings (in Pakistan, by neighbourhood and caste, in Zambia, by primary spoken language)	Discrete
- Collected during the final three visits after crossover	Primary and secondary water sources	Best and worse sources ◊ Sources regularly consumed without treatment ◊ Seasonal variation in sources	Categorical
	Water storage	Quantity ◊ containers ◊ protection	Quantity: Litres Remaining: categorical
	Water treatment	Whether, when, by what method, from what sources, and how frequently treatment is needed ◊ What causes contamination and how one can tell ◊ Typical treatment habits, including whether the primary caregiver grew up in a household treating water, and what methods were most commonly used prior to the study ◊ How methods compare to PoW/Pureit ◊ Affective feelings during treatment *	Categorical
	Emergency experience	Whether household was present during emergency events ◊ whether household suffered directly due to emergencies ◊ Any differences to treatment during emergencies	Categorical
	Household dynamics *	Who treats in the household ◊ what happens in absence of main treater(s) ◊ whether family is united related to product feedback and support	Categorical
	Social norms	Product preference of main social groups ◊ frequency of discussions regarding health and water* ◊ Relation to project team and community volunteers	Categorical
	Changes over study duration	Was water treatment harder or easier with time ◊ What became easier/ harder/ per product ◊ Is there a set time for treatment? ◊ What made HH treat more ◊ What made HH treat less ◊ How were our visits perceived over time ◊ How were community	

		volunteer visits over time?* ◊ Did trust for the product and project change with time?* ◊ Did weather shifts affect usage? *	
	Hygiene and sanitation	Stated frequency of hand-washing ◊ presence of soap ◊ latrine type and maintenance	Categorical
	Health knowledge	Water-related risks ◊ main community health risks,	Categorical
	Economic situation	Asset list including household material, rooms, vehicles, and animals ◊ Profession ◊ Stated monthly income and expenditure	Income/expenditures: local currency Remaining questions: Categorical
	Questions related to bias	Whether households were in study for the supplies as opposed to treatment ◊ How affected households were by visits ◊ If households would use the product in future ◊ Whether households were biased by visits	Categorical

◊ *separator*

* *only collected in Pakistan*

** *only collected in Zambia*

Water samples

Households were asked to indicate whatever water they were currently drinking. Enumerators would collect a sample if households confirmed that it had been treated with Pureit or PoW. If the first source provided was not treated, households were asked about any other treated sources available. Samples were tested across four physico-chemical parameters: pH, turbidity, free chlorine and total chlorine, and the reported time of treatment was also recorded. Chlorine residual tests were conducted in duplicate for each water source, and pH and turbidity were tested once. We did not test water that was not reportedly treated as the focus was on measuring Pureit and PoW performance as opposed to general household water quality. Furthermore, water quality was primarily established by measuring chlorine residuals in drinking-water, not microbial levels, and Pureit and PoW were the only source of chlorine in both study sites at the time of data collection (based on information from Oxfam Gb and their local partners, as well as confirmatory tests conducted by the study team, taking repeated measurements at each water site during project implementation).

Free chlorine (henceforth abbreviated as F.Cl), total chlorine (abbreviated as T.Cl), and pH were tested using a Palintest Standard Comparator Kit ® (PT 220, Palintest Ltd, UK). A single test for any one of these parameters was carried out by adding one of three reagent tablets (one per parameter) to a 10ml aliquot of sample water in a volumetric tube, and observing the resultant colour change, if any. The colour change was matched by eye to that of a control tube (with sample water, but no tablet) overlaid by a colorimetric disc which indicated the concentration of F.Cl, T.Cl, or the pH level. A DPD 1 ® tablet was crushed and dissolved in 10ml of water to measure F.Cl, and matched to the appropriate shade of the colorimetric disc after 2 minutes. The same sample solution was supplemented with a DPD 3® tablet to measure T.Cl concentration after a further 2 minutes. A fresh water sample was taken to test pH, in which a tablet of Universal Indicator® was dissolved, and tested against the pH-specific disc. Discs measuring chlorine residuals were able to detect free and total chlorine from 0.1 – 1.0mg/L (in 0.2 mg/L increments), and from 1.0 – 5.0 mg/L (in 0.5 mg/L increments). The disc measuring pH could detect pH from 0 – 14 in increments of 1 pH unit. The chlorine detection limit of the Comparator Kit was 0.1mg/L, but in practice this was difficult to distinguish from any value below 0.2 mg/. Values below 0.2 mg/L were therefore considered to represent non-detectable chlorine residuals.

Turbidity was measured using a Wagtech ® two-part turbidity tube (Palintest Ltd, UK), with a capacity of 300ml. A water sample was poured into the tube until the "X"-marking at the bottom of the tube was no longer visible – the level of water at which visibility disappeared indicated the turbidity, in standard Turbidity Units (TU).

3.1.3.2 Qualitative data collection

Overview

Qualitative research was designed and implemented as a secondary, complimentary and subsidiary component to the quantitative methods outlined above. Methods included focus group discussions (FGDs) and semi-structured interviews (SSIs), conducted within a purposively selected subsample of the study population. A small number of preliminary FGDs were conducted prior to the survey (pre-survey FGDs), followed by more in-depth FGDs and SSIs towards the last visit of the second crossover period (end-of-survey FGDs).

Rationale

The methodology adopted for the design and analysis of the study's qualitative component was primarily based on Green and Thorogood (2013) and Creswell and Clark (2007). Guidance on certain practical elements to conducting FGDs and SSIs was obtained from a RAND Corporation training manual specific to FGDs and SSIs (Harrell and Bradley, 2009). The addition of FGDs and SSIs to our survey qualified our overall study design as a mixed-methods assessment, following a "triangulation design procedure" as defined by Creswell and Clark (2007). The authors note that mixed methods can "bring together the differing strengths and non-overlapping weaknesses of quantitative methods (large sample size, trends, generalizability) with those of qualitative methods (small N, details, in depth)"(Creswell and Clark, 2007). The "convergence model" is a variant of the triangulation design, whereby quantitative and qualitative data are collected on the same phenomena and analysed separately. Their respective results are "converged" in the final interpretation of these findings. Qualitative data was largely used to expand upon quantitative findings, including in a way that might provide a different and divergent interpretation.

The more open, natural context of group discussions and semi structured interviews was explored to provide both breadth and depth to the same issues covered in the survey, recognizing that the process of answering and administering a questionnaire can be relatively rigid and create a somewhat formal context. The emphasis was on obtaining breadth of information, on assessing majority and minority views, and on whether feedback was confirmatory or deviant to questionnaire findings. The two approaches used – FGDs and SSIs – essentially covered the same topics, though it was speculated that one of the two may be preferred in each setting, that a broader range of feedback might be observed in FGDs, and that more deviant opinions might be obtained in the more private SSIs.

Data collection

FGDs took place at local meeting points within each community, and SSIs were conducted in respondents' homes or front yards. Pre-survey FGDs aimed to be representative of a broad cross section of the target population. Enumerators helped select participants for end-of-survey assessments, using purposive sampling to obtain a representative selection of community members and a wide range of feedback (i.e positive and negative product feedback, from high and low users).

FGD participation in both countries was mixed in terms of gender participation, though participation was biased towards primary female caregivers, as it was for the questionnaire, as they were the most involved in household water treatment. Younger females, younger males, and male heads of household were also represented, though in a minority. Greater representation of males was observed in Pakistan, where more men worked in the community, as opposed to the more urban setting in Zambia where men would often travel far for work.

Pre-survey FGDs aimed to obtain a range of basic details on the social and physical environment of the study, focusing on water sources and treatment habits. They were also intended to act as a mutual introduction between the study team and community, and an "ice-breaker". Small amendments were made to the questionnaire based on these findings. The end-of-survey FGDs and SSIs collected the most critical information within the qualitative methods used after a better relationship had been built with the community.

Qualitative data collection was conducted by a subsample of the project's enumerators who had demonstrated good social skills, as well as observational and interview skills. They were given further training prior to qualitative data collection, based on RAND FGD and SSI guides (Harrell and Bradley, 2009). Topic guides were prepared by the lead researcher, and specific questions developed around key thematic groups. Follow-up questions were suggested in the topic guide if needed, and facilitators could also investigate new areas of information raised by respondents. Opening questions followed a structured format, and facilitators would use probes, following answers up until a clear understanding was achieved of the object of the opening question. Questions were divided into three components: 1) introductory topics (of peripheral interest, aimed to act as a "warm up"), 2) central topics, of core interest, and 3) a concluding section asking respondents if there was anything else they would like to add or ask. Pre-survey FGDs focused on major water related practices, including treatment, general community concerns, and health-related behaviour. End-of-survey research focused on three key areas: self-reported determinants and barriers of usage, project feedback, and positive and negative product feedback. The main topic guides are summarized in Table 3.2.

A consent form was presented prior to all FGDs and interviews including an outline of the proceedings. Audio recordings were taken for transcription into English by enumerators, and analysed by the lead investigator together with field notes. Interviews were conducted by two enumerators, one going through the semi-structured questions, and another managing voice-recording and transcribing salient points raised during the interview. FGDs were conducted with between 8-15 participants, include males and female adults, or young adults. They were conducted by two enumerators, one designated as the lead, carrying the discussion forward, and the other as note-taker, who was also responsible for voice-recording. After interviews and FGDs were completed, the two enumerators in charge debriefed each other, going through the main points noted down, and making any amendments needed. English transcriptions of recorded FGDs and interviews, key observations by a dedicated note-taker present at each session, and field notes were all analysed by the lead investigator.

Country-level differences

Overall, six semi-structured interviews, nine post-survey and two pre-survey focus group discussions (FGDs) were conducted in Pakistan, while 14 post-survey interviews, one pre-survey FGD and two post-survey FGDs were held in Zambia. In Zambia the target population was more widely distributed across a particular "zone" of the urban "compound" (settlement), making households less familiar with other members of the study. The busier, more urbanized culture in this urban slum made it more challenging to get households to meet at central locations at given times. Households also appeared to be more comfortable divulging deviant opinions in private. All interviews took place on the household premises. FGDs were conducted at a local church, which was also a school and community centre. Pre-survey FGDs were conducted on the same day that households were provided with training and supplies after recruitment (see section 3.1.4). Groups of 8 - 10 individuals were selected at random from the wider group of attendees during product distribution, with one member per household. End-of-survey FGDs were conducted in communal areas with neighbouring households.

In Pakistan, the selected community was chosen in its entirety (as detailed in section 3.1.4.3). There was a culture of group discussions (*"kacheri"* in Sindhi), for which dedicated communal areas were often constructed (typically a single open plan room; *"autaak"* in Sindhi). Households preferred such meetings to individual interviews, and were comfortable expressing even deviant opinions. This country study thus included more end-of-survey FGDs than SSIs. All FGDs took place at the neighbourhood cluster level, where respondents were most comfortable with each other.

Table 3 2 Summary of qualitative topic guides

Method	Topic sections	Topics	Country differences
Pre-survey FGDs	Introductory	Main occupations	Mention of flooding in Pakistan, and cholera in Zambia
		Education levels	
	Water	Main sources and typical routine	
		Treatment frequency, methods, and reasons	
	Key priorities for community		
	Main health issues	What causes diarrhea and how can it be stopped	
	Key decision makers and opinion leaders		
	Habits	Daily habits	
		Habits that should be practiced but are not	
		Habits that have changed with time	

End-of-study Interviews and FGDs	Introductory questions	How water quality and supply changed during study	Focus on standpipes in Zambia, and river water in Pakistan.
		Key community concerns	
	Product feedback	Product preference, and reasons	More discussion related to health effects in Pakistan, given greater concern raised in the first crossove period (see Chapter 5)
		Suggested improvements	
		Variations in usage over time, and reasons	
		Feelings related to the products and their usage	
	Health	Waterborne diseases, and causes of diarrhea, awareness of WASH interrelation	
		Health effect of products if any	
	Trust	For products, team, and project	
	Social	Effect of relationship to team, discussions with other respondents on usage	
	Bias	Importance of courtesy bias, visits, concerns for future aid	

3.1.4 Implementation

The study sought to select sites and communities that represented typical settings where Oxfam GB could use flocculant-disinfectants in short-term settings. Implementation was designed to broadly replicate the method adopted by Oxfam GB and their partner NGOs in short term water treatment projects. In order to approximate a baseline estimate of adherence in short-term settings with minimal external influence, the study aimed to remain as unbiased as possible regarding adoption of either of the products, and did not include any overt encouragement of behaviour change.

3.1.4.1 Field activities:

Study activities could be grouped into four main categories:

1. Planning and implementation, including: hiring and training staff, site selection; obtaining local clearance; purchasing supplies; recruiting households and training them in product use; and distributing supplies
2. Eight weekly follow-up visits including: administering the repeat-measures survey during four visits per crossover period, for two crossover periods. The study followed a six-day week in order to visit each household on an approximately weekly basis.
3. Qualitative methods, including: pre-survey FGDs (prior to survey visits), and end-of-survey FGDs and semi-structured interviews (during and shortly after the 8th visit of the survey).
4. Project closing: including consolidating data, providing households with soap as a token, summarizing qualitative findings, and finalizing data entry.

Box 3.1: Overview of field activities

Preparation/Implementation
Orientation + Hiring staff + staff training + pretesting
Full scale product implementation + initial focus group discussion

Crossover phase I
Visit 1: Repeat questions + water samples + sachet counts + preliminary focus group discussions (subsample)
Visit 2: Repeat questions + water samples + sachet counts
Visit 3: Repeat questions + water samples + sachet counts
Visit 4: Repeat questions + water samples and sachet counts + non-repeat questions + demonstrations

CROSSOVER
At the end of Visit 4, the second product was given to households

Crossover phase II
Visit 5: Repeat questions + water samples + sachet counts
Visit 6: Repeat questions + water samples + sachet counts
Visit 7: Repeat questions + water samples + sachet counts + non-repeat questions + interviews (subsample)
Visit 8: Repeat questions + water samples + sachet counts + non-repeat questions + interviews (subsample) + closing focus group discussions (subsample) + demonstrations

Project close
Budget closing
Data consolidation
Field site exit

3.1.4.2 Ethics

Clearance was obtained from the following official bodies:

- LSHTM Observational / Interventions Research Ethics Committee in August 2012 (Appendix A). This was in turn contingent on:
    - A No Objection Certificate from the Lusaka City Council in coordination with the Lusaka District Health Management Team, which was contingent on:
        - Quality control tests to the satisfaction of the Zambian Bureau of Standards.
    - A No Objection Certificate from the Office of the Deputy Commissioner in Jamshoro district in Sindh, Pakistan.

PoW has been approved by the USEPA, and Pureit, by the Indian Food and Drug Administration. Oxfam commissioned a laboratory effectiveness trial prior to this study, establishing log reduction values within WHO guidelines across a range of challenge settings (Marois-Fiset et al., submitted).

Consent

A one-page household-level consent form was attached in duplicate to each questionnaire. The form was read out verbatim by enumerators to the self-defined head of household. Consent forms were simply worded while clearly stipulating key information for households to be aware of. If accepted, both copies were signed by the enumerator and respondent. One copy was retained by the household, and the other by the project team. If respondents were unable to write, enumerators wrote their name, and took a thumb print from the respondent. The form included:

- the scope of the project: to assess how the target population, and communities like them, responded to the two products
- assurance that the products were safe;
- information that the project was conducted in collaboration with local organizations and approved by local authorities
- a request for approval to include basic demographic and health information from all household members, including children
- assurance that household contact details and names would be kept private and not included in data analysis or publication
- contact details for the lead researcher

- an overview of what would be provided (sachets and equipment to treat water with)
- an outline of project duration
- details of household interviews (time requirements, number of visits, water samples)
- a stipulation that households could use the products as much or as little as they liked, and that the study was chiefly interested in their honest feedback, whether positive or negative.

Consent forms were also obtained from each semi-structured interview respondent, and in a group form for each focus group discussion. These forms stipulated the time that would be required, the broad area of discussion (project and product feedback), and a request to allow facilitators to take notes and audio-record the session. Each form included the date and time, the name of the facilitator(s), as well as the name and signature/ thumb print of each respondent.

No financial or other incentives were provided to households, besides water treatment supplies (see 3.1.4.5). At the end of the study, each participating household was provided with a bar of soap as a token, though they were not informed that this would be given prior to the event.

3.1.4.3 Site selection

Country selection

Country site selection was purposive, selected by Oxfam GB, whose country programmes were to host each project, characterizing it as part of their programmatic research. Key considerations included:

1. for the study to take place in settings where Oxfam GB country offices could envisage using Pureit or other flocculant-disinfectants, notably areas with a history of emergencies where drinking-water could be of high turbidity and microbial contamination;
2. for the study to cover more than one type of demographic background, in more than one geographical region, ideally including urban and rural, as well as Africa and Asia,
3. for country offices to have the capacity to host and support a small research team.

A range of Oxfam GB country offices were considered, including Bangladesh, Nepal, Pakistan, Liberia, D.R Congo, and Zambia. Oxfam GB Pakistan and Zambia were the two offices with the best availability. Oxfam GB's Sindh office was a local regional centre, originally set up to respond to the floods in 2010 and in 2011. Activities were mostly in rural Sindh and Balochistan, where the primary water source was often surface water. Oxfam GB's Programme in Zambia was headquartered in Lusaka, where many low-income settlements experienced seasonal cholera outbreaks. Such settlements often used a combination of water sources, including public standpipes and shallow dug wells(Grönwall, 2011).

Community selection

The project was housed in Oxfam country offices that provided logistical and administrative support to the project, while fieldwork was conducted by a team that was hired and trained for the project by the lead researcher. Oxfam GB programme managers and staff from their partner NGOs provided support for site selection, visiting a number of sites with the lead researcher, who made the final decision based on the available choices. Site selection criteria included the need for:

- Water sources that were
    - Considered appropriate for flocculant-disinfectant POU treatment by Oxfam GB WASH programme officers
    - known by Oxfam GB and their partners to be high turbidity and/or microbially contaminated
    - free of residual chlorine
    - known by Oxfam GB and partners to be associated with waterborne disease
- A distance that was within daily commute of the project headquarters (Oxfam GB offices)
- Familiarity with Oxfam GB and/or partner NGOs. This was to meet Oxfam's requirement to character the study as programmatic research, and to allow for rapid implementation and integration within the community
- Communities that indicated a need for better provision of drinking-water and accepted the study taking place
- Sufficient households to meet sample size requirements

Zambia

Two possible sites met the selection criteria in Zambia, both of which were in Lusaka. The ideal candidate in terms of water source contamination and vulnerability was part of an on-going study by another LSHTM research project, and thus the study took place in the second site. This was a large low-income settlement, or "compound", with over 100,000 inhabitants (Chilufya, 2013). The area had been planned in the colonial era, though later densified to an extent where the underlying infrastructure was insufficient, and basic energy, water and sanitation were inadequate(Grönwall, 2011). The study took place towards the end of the hot season and saw the onset of the rainy season. Though a marked temperature change coincided with the product crossover, the rain only began towards the final visit of the study. Households traditionally relied on shallow dug wells of reportedly high turbidity and microbial contamination (Grönwall, 2011). However, public standpipes had been installed between 1994-2000 (UNOSSC, 2005), and were the primary water source for most households. Standpipe water was available at specific time intervals for a flat monthly rate. Shallow dug wells still accounted for the main secondary, supplementary water source in the community during this study. Other sources included private water vendors. Standpipe water was centrally treated by the Lusaka Water Company, though local administrative bodies advised that no chlorine residuals had been found at-tap, and that sporadic contamination was common. This study also found no chlorine residuals during confirmatory source water tests (n=20 standpipes in the target area, *data not shown*). Though the study site's reliance on piped water was not ideal for this study, standpipe water was of variable quality, households also used shallow well water, and cholera was seasonally endemic (Chilufya, 2013). The study site has been the focus of prior studies, many related to diarrheal disease and safe water (Ashraf et al., 2010; Olembo et al., 2004). Oxfam GB's Programme in Zambia would support the local community administration annually with the provision of liquid chlorine solution at standpipes in the rainy season (*L Katsi K, D Judge, personal communication* Oxfam GB Programme in Zambia). Figure 3.2 includes pictures of the main local market, and a study participant with both products and supplementary supplies at the end of the study.

Figure 3 2: Study site (Lusaka, Zambia)

Study site, Lusaka Zambia

Study participant

Pakistan

Two potential sites in Pakistan met the selection criteria related to location, water quality, and population size. The site that was finally selected had been worse-affected by the nationwide flooding in 2010 and regional flooding in 2011, being on the banks of the Indus River (Gaurav et al., 2011; Haq et al., 2012). The site was situated on the outskirts of a rural town within daily commuting distance from Oxfam GB's regional office in Hyderabad, along the banks of the Indus River. The community had received support from Oxfam GB and their local partner the Research and Development Foundation (RDF) in post-flood recovery activities, receiving medical aid, food, water, and infrastructural support (Oxfam GB Sindh office, *personal communication*). The first month of the study was during the end of the hot season, and the onset of winter began in the second month (after the crossover). The primary drinking-water source was river water that was pumped, stored and piped through an informal piped network with no prior chemical treatment. Water was received on the premises through in-yard taps and a small number of standpipes. Pipes syphoned water from a pump used by the neighbouring industries, with only a basic filter to prevent large debris from entering the system. Approximately one third of the households used a standpipe, over half used an in-yard tap, and the remainder had taps within the household. The ultimate source of the different delivery points was considered to be the same for all households (river water), as neither underwent further treatment. Water was commonly stored in containers on rooftops and in the yard, where river water was allowed to settle and sometimes treated with alum rocks (aluminium sulphate) and simple cloth filtration. In addition, a nearby industrial site had set up a standpipe next to their complex as a goodwill initiative, providing chlorinated water for free. As this necessitated a 40-minute return trip from the community as well as collection and transport, it was not considered to be a regular source, mostly reserved for emergencies. Figure 3.3 includes pictures of a neighbourhood in the community, and two study participants demonstrating product usage.

Figure 3 3:Study site (Sindh, Pakistan)

Study site, Sindh, Pakistan

Study participants

3.1.4.4 Community-level implementation activities

Community approach and volunteer recruitment

After finalizing site selection, preliminary meetings were held with community leaders and mobilizers. These were followed by group information sharing activities, to introduce the project to the community. Social mapping exercises were practiced to get an understanding of community size and makeup. Households were then recruited into the study through door-to-door visits. Local community volunteers were used to assist in certain aspects of the study, as per Oxfam and their partners' usual protocol in community-level projects. These were individuals who had typically supported previous development initiatives, and were often part of local organizations. Community mobilizers were the first members of the community trained in product usage. They helped mobilize community members, recruit households, and train them in product usage. They acted as guides during initial household visits (though not remaining present during interviews), and as a communication bridge between the community and team.

Pretesting

Pretesting was conducted within a small group of households within similar environmental contexts to the target population. In Zambia, a small neighbourhood with 20 households in a different zone (approximately 1km away) of the same compound was selected, and were given three days supplies of the products (half were provided one and half the other), after providing them with training in usage on the first day. The team administered their questionnaires two days later, with each enumerator covering approximately three households. In Pakistan, a small settlement working with the partner on another project situated within 1 km of the target site was selected for pretesting. The site consisted of 30 households, each of whom was provided with 3 days worth of one of the two products. Enumerators administered the survey on the third day after usage training and supply distribution.

Household recruitment

Household selection criteria was purposefully broad to be inclusive of a wide range of potential users. The criteria for household selection was for 1) the self-identified head of household or primary caregiver to give consent for household participation in the evaluation, and 2) study participants to expect to live in the same location for the period of the study. The relatively large compound selected in Zambia was divided into several administrative blocks, or zones. A particular zone was chosen, based on input from Oxfam GB, the formal local community development organization ("ward development committee"), and the local health centre, who noted its relatively higher proportion of shallow well users, and higher rate of seasonal cholera during previous epidemics. A rough mapping of households and streets in this zone was conducted with the field team, as no reliable and recent population estimates were available. It was estimated that every eighth household from within the selected zone could be invited for recruitment. Each street from the mapping exercise was numbered, and pairs of enumerators were randomly allocated an equal number of streets to visit. Every eighth household was visited from the top of a given street, and in the event of refusal or absence, immediate neighbours were approached. This activity continued for two days until full coverage was established. In Pakistan, the selected community was included in its entirety, through door-to-door visits.

Product distribution

After obtaining their consent, participating households were given tokens and a time and location to receive product training and project supplies. Distribution was conducted in batches, and was assisted by community mobilizers. The central training point in Zambia was a local church that was active in the target zone in community work and education. In Pakistan, trainings took place in every neighbourhood, as the community was fully covered, and clearly divided by neighbourhood, which were divided along lines of caste. Implementation was designed to broadly replicate the protocol for short-term point-of-use water interventions used by Oxfam and their partner NGOs (*N.Bazezew, L.Katsi, S.Baloch Oxfam GB, personal communication*). Training did not go beyond group explanations of product usage, and did not include strong messaging to increase potential behaviour change. Households were given thorough explanations on product use, specifically differentiating the two products and all safety information. A list of all households was compiled after recruitment, and used to randomly allocate households to the first product in such a way as to have two equal arms. All households were also given complimentary items to use the product with, as per Oxfam protocol, and in order to ensure comparability of results across households and sites. Supply distribution and data collection took place at the household level, defined as a family unit that shares daily drinking water and live together on a regular basis. This was relatively simple in Zambia where households were physically separate and participants were randomly selected over a wider area. The community selected in Pakistan was fully covered.

Participating households were given:

- 1 x 10L bucket
- 1 x 1m^2 cotton cloth
- 1 x 10-12L safe storage container, with a tap for drinking-water and a lid to protect it

- 1 x stirring spoon (wooden or metallic)
- 1 x brochure with pictorial explanations of the given product
- Sufficient sachets of either PuR or Pureit to last one month.

Each household was given one month's set of the allocated product, at the beginning of each four-week usage phase. Households in Zambia were given 93 sachets per phase (based on 3 sachets/household/day for 31 days). After observing usage in Zambia, households in Pakistan were given 62 sachets per phase (2 sachets/household/day for 31 days). Households were asked to retain all used and unused sachets in containers provided for this purpose, and informed that they would be provided more if they ran out.

Language

As the official language in Zambia is English and the common spoken languages in areas like the study site are a combination of dialects, the study tools remained in English, as designed by the lead field investigator. The study team worked together to find consolidated terms to implement the questionnaire in both Town Nyanja (Lusaka's main dialect) and Bemba, where appropriate. The team developed a draft questionnaire in each language using English script, and kept copies with them during visits for reference. Actual surveys were administered using the English version finalized by the lead researcher. In Pakistan, the questionnaire was entirely translated in Sindhi, using Urdu script. This was developed by the team and with support from Oxfam's partner NGO. In both country studies, enumerator training included considerable practice sessions of survey administration, during which time small changes were often made to the questionnaire, based on enumerator feedback.

3.2 DATA MANAGEMENT

3.2.1 Data quality

Questionnaire data went through three stages of quality control. Completed questionnaires were proofread at the end of each day of data collection by the enumerator who administered them, following which they were double-checked by the field supervisor and/or lead researcher. Any revisits needed to amend mistakes identified in this process were conducted at the beginning of the next day of fieldwork. Data entry served as a final quality control stage, with consultations between entry staff and enumerators to clarify apparent contradictions or gaps in data.

Each FGD and SSI was followed by a debriefing session between the two facilitators who would compare notes. Findings from field notes were further cross-checked during transcription of each qualitative session.

3.2.2 Data entry

Data was double-entered in Epidata 3.1 (Epidata Association, Denmark). After entry, the two entries were validated and entry staff would consolidate any differences found. Data was entered in separate files for each study visit.

Qualitative data field notes and transcriptions were compiled by the facilitators of the qualitative sessions on a computer in project headquarters.

3.2.3 Privacy and safeguards

Questionnaires, FGD and SSI forms were stored in a cupboard which was locked by the lead researcher. Household contact details were kept on the hard copies of the questionnaires to facilitate fieldwork, though not entered during data entry. Only the first name of the head of household was entered during data entry as an identifier in case of any entry errors, and dropped from the final files after consolidation. Though demographic information was included on all household members, their names were not entered in Epidata. Data was entered on two computers in Oxfam GB country offices that were password-protected. Qualitative data transcriptions, facilitator notes, and audio files were also stored on one of the two entry computers. All files were backed up on two USBs, password-protected and kept by the lead researcher. Questionnaire hard copies will be safely stored for a period of two years.

3.2.4 Data cleaning

After consolidating double entered data, Epidata record for each visit were merged according to unique household identifiers and transformed to a format readable in Stata (Statacorp, TX). All data cleaning and analysis was conducted by the lead researcher on Stata 11 (personal copy) and Stata 13 (LSHTM version).

3.2.5 Management of key outcomes

This study focussed on three key categories of outcome: used sachet data, water quality metrics, and covariates that were potential predictors of usage. The word "adherence" is used in the same manner as "compliance" in much of the POU evidence base, and for the purposes of our analysis, refers to sachet usage over a given period of time. "Usage" refers to sachet usage at a single point or over several points in time, depending on how it is specified in context.

Water quality data

Analysis of water quality data used the mean of each water sample's duplicate free and total chlorine measurements. Extreme differences between the duplicate measures in each sample (i.e free chlorine residuals from the same sample reading <0.2 mg/l and 4 mg/l) were double-checked by referring to hard copies. Enumerators were instructed to take a water sample from any household container with reportedly treated water. In practice, only the first sample collected at any given visit was tested, as only two per cent of households also presented a second water sample.

Used sachets

The primary outcome employed to assess usage in this study were observed used sachets. Households were requested to keep all used and unused sachets for the entire duration of the study. Enumerators counted all used and unused sachets at every visit. Households were asked to account for any lost sachets, if the total number of sachets differed at any visit. Options were given in the survey for sachets that were "used but lost", "unused but lost", or "shared with other households". In the second crossover period, households were also asked if they used any products from the previous period. Households were also asked to estimate how many sachets they had used, as a daily average in the past week, as a self-reported measure.

The primary objective outcome of sachet usage was "sachets used per visit" (broadly equating to "sachets per week"). This was the difference between used sachets at a given visit (including "used but lost"), and the prior visit – except for the first visit where all used sachets sufficed. A number of outliers were found in used sachets per visit, including extremely high results (e.g >30 sachets used since the last visit), and negative values (where enumerators somehow counted *less* total used sachets during successive visits). In the case of the former, all weekly used sachet values above 30 sachets were investigated by cross-checking soft data with hard copies. Approximately 8% of final values were observed to be this high in a manner that couldn't be accounted for by error or by the number of days that had elapsed between visits. These were retained in the main analysis of Chapters 4 - 6 as they were accurately determined. Analysis was also conducted without these values to assess any differences; no significance difference was found.

Changes to sample size

Given the changes in sample size due to loss-to-follow up and data issues, slightly different denominators can be found based across different visits and types of subsample analyses. The maximum sample size employed in this manuscript's analysis was 233 households, and the minimum was 215. Five pairs of households (n=10) were found to have actually been joint households, where the same water source was used. These households were completely excluded from the analysis as sachet counts and product allocations could not be clearly accounted for. A further 11 households left the study at some point in the study, mostly (7/11) due to a lack of interest in using the products, while the remainder had to leave the community for an extended period of time. Three households left the study, stating not wanting to use the products anymore, but then returned after changing their minds.

The maximum number of households included in this manuscript's analysis was 204, and the minimum 190. The main follow-up issue faced in Zambia was that the population was highly mobile. Few households owned their own house, and many changed housing within the study duration for financial or professional reasons. The maximum number of households included in the Zambia dataset was 204. This was after 10 households could not be found directly after recruitment, having vacated their houses. A further six households (3% of the maximum sample size) left the study during the follow-up period, half of which was due to shifting houses, and the other half were no longer interested in treating their water or being visited. Used sachet data were negative for some visits within thirteen households (6% of the maximum sample size). One household left the study site for two visits and then returned.

3.2.6 Overview of analytical methods employed

This section presents an overview of the basic analytical methods used in the three results chapters (Chapters 4 - 6). Specific analytical procedures and details are the subject of each chapter's individual Methods section.

3.2.6.1 Qualitative analysis

Analytical steps

A relatively deductive approach was taken, based on framework analysis as outlined in Green and Thorogood (2013). The key steps followed were:

1) Familiarization, i.e reading each transcript and all field notes several times to gain familiarity with the raw data

2) Thematic analysis, i.e developing thematic codes for responses.

3) Indexing, i.e applying codes to the data

4) Charting, i.e rearranging data by theme and summarizing findings

5) Mapping and Interpretation, i.e developing a framework for the interrelationship between key findings, and interpreting findings in context.

These steps were modified in light of the relatively well-defined format that questions followed. Steps 3 - 5 were conducted within thematic groups that were largely based on topic guides (Table 3.2), and answers were summarized as to whether they were provided by a majority or minority of respondents. Feedback was summarized combining both FGDs and SSIs, according to the main concordant and discordant responses, and the broad frequency of given responses. Qualitative findings were presented as thematic summaries which included feedback from both FGDs and SSIs. Responses were qualified as being reported by a minority or majority of respondents, and included representative quotes where applicable.

3.2.6.2 Quantitative analysis

Outcome overview

The major outcomes in this study were used sachets, and chlorine residuals, analysed in the form of raw count and ordinal categorical data. Raw used packet and chlorine residual data were highly right-skewed, requiring non-parametric analyses of variance and hypothesis tests, and regression models that did not assume a Normal distribution. In a few cases, outcome distributions differed between the two country datasets, requiring slightly different models for evaluations of the same research question. Most outcomes employed in this study were collected over several repeat visits (e.g used sachet counts), requiring analysis to be clustered at the household-level. Most statistical tests employed Stata's survey data (*svy*) function to account for this. All numerical outcomes in this manuscript are presented within two significant figures.

Hypothesis tests and analyses of variance

We used non-parametric analysis of ordinal association to conduct basic hypothesis tests for our non-Normal outcomes (e.g raw used sachet counts, raw chlorine residuals, categories of daily sachet use, categories of residual concentrations). Typical non-parametric tests of association such as the Wilcoxon Signed Rank test and Kruskal-Wallis one-way analysis of variance cannot be employed with clustered data (Heeringa et al., 2010). An approximately equivalent ordinal measure of association between two variables is the Somer's D (somersd in Stata 13) developed by Somer's (1962) and developed for Stata by Newson (2002) . Somer's D could be used for two-way hypothesis tests, as well as one-way analyses of variance (Newson, 2014, 2002). In a few cases (i.e Chapter 5), non-clustered data was used as the outcome (e.g total used packets per phase), and two-way hypothesis tests were conducted based on the distribution of the outcomes, including T-test or Wilcoxon Rank Sum tests. The null hypothesis for all statistical tests in this study was formally rejected for probability values less than 5% ($p<0.05$), though probabilities between 5 and 10% were considered to be of borderline significance ($0.05<p\leq0.1$).

Regression models

Methods for the regression models were primarily informed by Heeringa et al's textbook on Applied Survey Data Analysis(Heeringa et al., 2010). Models used in this study include: zero-inflated- and normal negative binomial regression, ordered and generalized ordered logistic regression, and logistic regression. All models were run with the *svy* survey option to account for clustering of repeat visits per household.

Negative binomial regression and zero-inflated negative binomial regression (*nbreg and zinb* commands in Stata 11, respectively) were used to assess raw numbers of weekly sachet usage. These models were employed after investigating several possible alternatives for count data, including log-transformation for linear models, Poisson models, zero-inflated Poisson models through the consideration of goodness-of-fit measures and residuals (using *countfit*, *vuong*, and *gof* commands in Stata 11). Negative binomial regression, or "Nbreg" models are Generalized Linear Models that are an extension of Poisson models. They are appropriate for cases where the major assumption for Poisson models – equal mean and variance– is not met. Both Nbreg and Poisson models share the log link form of the Generalized Linear Model, though Nbreg includes a dispersion parameter alpha that relaxes the assumptions of equal variance and means. The two present similar values in cases where the variance and mean do not differ greatly. Nbreg effect sizes can be presented as Incidence Rate Ratios (IRRs), a ratio of rates of outcome in exposed and unexposed groups (a ratio of ratios, as it were)(Hilbe, 2008). An IRR value of X indicates a rate change in the dependent variable for a one unit increase in the independent variable. In the case of weekly sachet usage over all study visits, an IRR value of 1.5 indicates a 50% increase in the rate of average sachet usage for a one unit increase in the independent variable, while holding all other variables in the model constant.

Zero-inflated negative binomial regression, or "zinb" is a two-part alternative to Nbreg, including a logistic model (for zero counts) and a standard Nbreg model (for non-zero counts/positive integers). It is intended to address datasets with a relative abundance or "excess" of zero-counts, termed "zero-inflated"(Preisser et al., 2012). This can often be the case with count datasets where zeros represent significant findings. Examples from this study include the absence of chlorine in water samples, or the absence of sachet usage in the past week. In cases where 0s form a substantial proportion of findings, zero-inflated models may be required. Several authors have noted that zero-inflated models are to be used with restraint, and only if they provide considerably divergent findings from non-inflated models(Allison, 2012). Each independent variable in a zinb model is associated with two effect sizes, the odds of obtaining zero counts, and the incidence rate ratio for all positive counts. In the case of weekly usage, zero-inflated models indicate the odds of no usage (0 counts) and the rate of weekly usage (for all positive counts).

Logistic regression was employed in a small number of tests using binary outcomes (e.g the presence or absence of detectable chlorine residuals). Effect size coefficients were exponentiated to be expressed as odds ratios.

Given the clustered nature of this dataset, neither R^2 estimates nor likelihood ratio tests could be conducted (Heeringa et al., 2010). Wald's tests were used to assess the contribution of exposure variables to the outcome of interest. Wald's tests were particularly useful to assess the contribution of variables with several categories, and the two effect sizes that were associated with every variable assessed in *zinb* models.

Ordered logistic regression was employed for assessments of categorical outcomes with more than two categories, for outcomes such as chlorine residuals (Chapter 4) and daily sachet usage (Chapter 5). This method performs logistic regressions on binary combinations of the various categories of the outcome (e.g binary assessments of an outcome with three categories A B C would be A&B vs C and A vs B&C). All effect sizes were presented as odds ratios, signifying the odds of being in a higher category of the outcome for a unit increase in the independent variable.

Standard ordered logistic regression (*ologit* command in Stata) is based on the assumption of proportional odds, whereby the odds of being in any higher category of outcome to any lower category are assumed to be the same. For a three category outcome A B C, the odds of being in category C relative to A&B are assumed to be proportional to the odds of being in category B&C relative to A. An approximate likelihood-ratio test was conducted (using the *omodel* command in Stata) to test the proportionality of odds across response categories, with the Null hypothesis that coefficients across response categories are equal. In cases where the odds were not proportional the use of *generalized* ordered logistic regression is warranted(Williams, 2006). This form (using the *gologit2* command in STATA) calculates separate odds for each binary association. In a three category outcome, it would present both the odds of being in categories B&C relative to A, and of C relative to A&B (Williams, 2006).

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Chapter 4. Investigating the field performance of a new flocculant-disinfectant water treatment product in Pakistan and Zambia: a mixed-methods comparative crossover study

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SECTION A – Student Details

Student	Ameer Shaheed
Principal Supervisor	Sandy Cairncross
Thesis Title	A field performance and adherence study of point-of-use water treatment in Zambia and Pakistan

If the Research Paper has previously been published please complete Section B, if not please move to Section C

SECTION B – Paper already published

Where was the work published?	N/A		
When was the work published?	N/A		
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Where is the work intended to be published?	Journal of Water and Health; Water Science and Technology ; PLoS One (in order of preference)
Please list the paper's authors in the intended authorship order:	Shaheed A, Bruce J, Bazezew N, Bastable A, Doria C, Cairncross S, Brown J
Stage of publication	DRAFT

SECTION D – Multi-authored work

For multi-authored work, give full details of your role in the research included in the paper and in the preparation of the paper. (Attach a further sheet if necessary)	I took the lead role in data collection and analysis, as well as in drafting this manuscript

Student Signature: [signature] **Date:** 26/09/15

Supervisor Signature: Sandy Cairncross **Date:** 26/09/15

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ABSTRACT

This paper evaluates the field performance of two point-of-use (POU) water treatment products: the Purifier of Water (PoW) and the new Pureit sachet in peri-urban Sindh, Pakistan (n=233 households) and urban Lusaka, Zambia (n=204 households). A mixed-methods longitudinal crossover study design was employed, including a weekly survey administered over eight unannounced visits assessing physico-chemical water quality in user-reported treated samples. Focus group discussions and semi-structured interviews focusing on product performance feedback were administered to a subsample of households.

The median free chlorine residual level in all samples was 1.1 and 0.8 mg/l for Pureit and PoW in Pakistan, respectively, and 0.3 and 0.2 mg/l for Pureit and PoW in Zambia, respectively. Approximately 52% of all water samples collected in Pakistan, and 23% in Zambia contained free chlorine within minimum WHO-recommended concentrations for safe drinking-water. Water treated with either product in Pakistan was safe from recontamination for the first 12 self-reported hours since treatment, meeting WHO (0.2mg/) and SPHERE guidelines (0.5 mg/L). Both products only delivered safe water for the first 6 hours since treatment in Zambia, which would be considered unacceptable according to CDC, WHO and SPHERE guidelines. Country-level differences in product field performance were likely due to a combination differences in adherence, reporting accuracy, as well as source water conditions. Our findings also underlined significant product differences. Pureit-treated samples had significantly higher overall chlorine residuals in both countries ($p<0.001$), though did not maintain minimum levels of free chlorine any longer than PoW. Pureit also exhibited weaker buffering, with more samples in both countries that were between pH 8-9. Qualitative feedback gave critical insights into field performance that were not covered by water quality measures, including: Pureit's packaging being vulnerable to damage through handling, leading to unpalatable water; sporadic and short-lasting source water quality issues affecting flocculation and coagulation of both products; and challenges related to users following treatment instructions.

This study underlines the importance of carefully testing new POU products' field performance in real-world usage contexts. Our findings suggest that flocculant-disinfectants in short-term usage contexts may require implementation support given their relative complexity. We support efforts providing greater guidance for POU field performance recommending that such guidelines account for the dynamic nature of field performance and water quality over time, the close relationship between adherence and effectiveness, and the user-experience of treatment, including qualitative feedback.

4.1 INTRODUCTION

Treating water at the household-level, or point-of-use (POU) is one way of improving interim access to safe water for the 663 million (WHO/UNICEF, 2015) to 1.8 billion people (Bain et al., 2014) lacking it. A wide and growing range of POU products and technologies is available (Clasen, 2009; WHO, 2002). However, the current evidence base indicates considerable variability in adoption levels and health impact, among other challenges (Clasen et al., 2007; Fewtrell et al., 2005; Waddington et al., 2009). Successful POU products must be able to demonstrate adequate disinfection in controlled settings where contamination can be carefully quantified (i.e "efficacy"), as well as produce safe, acceptable drinking water in real-usage settings (i.e "effectiveness"). In contrast to notable challenges in POU adherence (Clasen et al., 2007; Waddington et al., 2009), the water treatment effectiveness of major HWT methods is less frequently questioned, often considered to be sufficiently established through efficacy assessments and trials (Clasen, 2009; Wolf et al., 2014). However, POU effectiveness is not clearly defined or uniformly measured, and a review of the evidence base suggests varying degrees of accuracy in measuring field performance. This study is the first field review of a new flocculant-disinfectant, comparatively assessed with a similar product in a multi-site crossover study conducted in urban Lusaka, Zambia, and peri-urban Sindh, Pakistan.

Effectiveness can be defined as: "[t]he extent to which a specific intervention, when used under ordinary circumstances, does what it is intended to do", to be distinguished from "efficacy": "[t]he extent to which an intervention produces a beneficial result under ideal conditions"(Cochrane, 2015). Field trials can be both efficacy or effectiveness assessments, and what constitutes one or the other can be subject to some debate, particularly when the choice of populations, site-selection, and implementation methods are different to what would be expected in a "real world" scenario (Glasgow et al., 2003). The term "field efficacy" is perhaps more accurate to describe many POU intervention studies, which often include a high degree of follow-up, active encouragement and behaviour change promotion, and take place over relatively short periods of time(Eisenberg et al., 2012; Glasgow et al., 2003).

Measuring POU performance in field settings is considerably more challenging than measuring efficacy, and the two can provide significantly different findings. Two of the most relevant studies in this regard were conducted by McLaughlin and colleagues (2009) and Levy et al (2014), assessing liquid chlorine disinfection in rural Ecuador. McLaughlin et al (2009) compared chlorine disinfection in users' homes to controlled laboratory tests on surface water in the United States, while Levy and colleagues (2014) assessed user-treated samples to water that they collected and treated at the same site. Both studies found real-world usage to be significantly less efficacious than assessments conducted by researchers (Levy et al., 2014; McLaughlin et al., 2009). Pickering and colleagues (2015) assessed the field performance of a passive chlorinator in Bangladesh, where their "real-world" longitudinal observations indicated lower effectiveness and challenges than expected from earlier more controlled tests (Pickering et al., 2015).

The differences between POU effectiveness and efficacy are largely due to individual usage-related factors, *in situ* product performance, and the inherent variability of real water sources, all of which are dynamic factors. POU products can function differently over time and based on maintenance. Filtration can be prone to clogging and breakages, liquid chlorine must be carefully bottled and stored, and solar disinfection bottles must be routinely cleaned (Boisson et al., 2010; Shaheed and Bruce, 2011; WHO, 2002). Microbial water quality changes on an hourly, daily and weekly basis within the same source due to environmental and human factors (Levy et al., 2008). The performance of methods employing chlorine is subject to several factors in source water including turbidity, pH, organic content, and temperature, all of which are spatially and temporally variable (Edzwald, 2011; Levy et al., 2009; WHO, 2011). Individual users are the fundamental operating force for any given POU method, and the primary recipients of the method's outcome – safe and palatable drinking water. To function as "intended" (Cochrane, 2015), POU methods must also include user-related considerations, including aspects such as usability, durability, and aesthetic considerations. A more appropriate and widely encompassing definition of POU effectiveness might thus be "field performance".

However the POU effectiveness evidence base includes a wide range of measurement methods and definitions, many of which may inadequately represent POU performance under real-world conditions. Several studies test water within only a subsample of their exposed population, and many take a single cross-sectional estimate of water (Clasen et al., 2007) . Where chlorine based products are used, many key covariates to contextualize chlorine residual findings may be excluded, such as pH, turbidity, or treatment time (McLaughlin et al., 2009). POU effectiveness goes beyond the efficacious disinfection of water, and must also lend itself to being performed properly, and providing water that is palatable as well as safe. The user-related element to POU water treatment is particularly less well covered, including aspects related to appropriate usage and maintenance, and measures that go beyond physico-chemical water quality characteristics such as aesthetic qualities and usability. Furthermore, a significant proportion of the literature is based on intervention trials that are primarily powered to assess the difference between exposure groups as opposed to measuring effectiveness within groups and over time(McLaughlin et al., 2009). Several interventions that found significant differences between intervention arms also reported some contamination in the treatment-arm (Brown et al., 2008; Lule et al., 2005; Semenza et al., 1998). If this was related to the POU methods not functioning "as intended"(Cochrane, 2015), it would count as reducing effectiveness, particularly given that even small amounts of exposure to contaminated water can greatly increase risk of waterborne disease (Brown and Clasen, 2012; Enger et al., 2013; Hunter et al., 2009).

There are no specific guidelines for measuring POU performance in field settings, though several recommendations emerge from a review of the literature. These include: covering as much of a target population as possible; employing longitudinal assessments to account for the considerable variability in water quality and adherence over time; including covariates directly related to water quality measurements, such as pH for chlorine-based methodologies; conducting studies in more "natural" usage settings, and including qualitative findings focusing on user-experiences (Arnold and Colford, 2007; Eisenberg et al., 2012; Fiebelkorn et al., 2012; Levy et al., 2014, 2014; Luby et al., 2008; McLaughlin et al., 2009; WHO, 2012).

This paper comparatively assesses the performance of two flocculant-disinfectants – or coagulant disinfectant product (CDP). The study was conducted over a short period of time (8 weeks) in settings with recent local histories of emergencies to approximate field performance in real-world short-term usage conditions. The products were Procter & Gamble's Purifier of Water ®, a well-documented flocculant-disinfectant (Chiller et al., 2006; Luby et al., 2006; Souter et al., 2003) – and Unilever Ltd's Pureit ® sachet, a new CDP to the market (assessed in prototype form, and since further developed). The premise for the Pureit sachet's added value was more streamlined treatment steps, and a less pronounced "chlorine taste" due to the partial quenching of free residual chlorine after an initial disinfecting spike. The main differences between the two products and further details are summarized in the supplementary material provided with this manuscript[1]. A longitudinal, mixed methods crossover design was implemented, employing a weekly quantitative survey measuring water-quality, product usage, and select covariates, supplemented by focus group discussions and semi-structured interviews. To supplement water quality measures and provide information on less quantifiable aspects of field performance including user perspectives, qualitative feedback on product usability and demonstrations of usage were also conducted.

[1] This text will be in the published version, and include the information provided in this manuscript in Chapter 1 (Section 1.4)

4.2 METHODS

4.2.1 Implementation

See Appendix B for an abridged version of study implementation that will be used in the published version of all three results chapters in this thesis, and Chapter 3 for further methodological details.

4.2.2 Data analysis

4.2.2.1 Quantitative analysis

The primary data explored in this paper were water quality measurements, focussing on chlorine residuals (T.Cl and F.Cl) and also pH, turbidity, and the availability of treated water (based on household self-reports), during unannounced visits. The relationship between these measures was assessed over time and between products. Significant differences were assessed using hypothesis tests and regression models. Using a crossover design allowed this study to assess differences between products within households, controlling for variation in usage practices, adherence and acceptability that may have affected assessments in a twoàarm trial. All regression analysis and analyses of variance were conducted after controlling for repeat measures within households.

Three key guidance documents were used to inform chlorine residual levels in this study (further elaborated upon in Appendix C: the WHO Guidelines for Drinking-Water Quality (WHO, 2011), the CDC Safe Water Systems handbook (CDC, 2000), and the SPHERE guidelines for emergency water treatment (Sphere Project, 2011). T.Cl is a more inclusive measure of the presence of chlorine in water, and was used as an objective indicator to validate user-reported treatment (within 24 hours). Samples with T.Cl residuals <0.2mg/L were assumed to have no chlorine, and thus to have potentially not been treated within the last 24 hours. The proportion of reportedly treated samples with detectable T.Cl was considered to represent "verifiable" treatment. Samples with F.Cl residuals ≥0.2mg/L were considered to be safe from microbial recontamination. The proportion of all household visits with F.Cl ≥0.2mg/L was considered to represent "effective use" as an approximation of Lantagne and Clasen's definition: the proportion of an at-risk population that have access to safe water(Lantagne and Clasen, 2012). Following the CDC guidelines, F.Cl values above 2.0 mg/L were considered to potentially be above the "taste-acceptability" limit and potentially unpalatable (CDC, 2000). Thus a benchmark F.Cl range of 0.2-2.0 mg/L was considered "ideal", comprising safety and acceptability, and the three main categories assessed in the analysis were: <0.2, 0.2-2.0, and >2.0 mg/L. Turbidity was recorded in turbidity units (TU). Values below 5 TU were considered equivalent to the ≤ 5 NTU used in water quality guidelines, though in practice, more precise methods may have yielded ± 5-10 NTU difference in findings (Dorea and Simpson, 2011).

Primary outcome data was collected longitudinally – over each repeat visit – per household. All analysis therefore controlled for clustering at the household level. Somer's D tests were used as a non-parametric analysis of variance that allowed for clustering, employed for all primary outcome measures (Newson, 2002). These tests were supplemented with ordered logistic regression models for categorical values of T.Cl and F.Cl (three categories: <0.2, 0.2-2.0, and >2.0mg/L). Effect sizes are presented as odds ratios, signifying the odds of being in a higher category of the outcome for a unit increase in the independent variable. As the assumption of proportional odds was not met in the Pakistan dataset, "generalized" ordered logit models were used (Williams, 2006) providing two separate outcomes: the odds of residuals having ≥0.2mg/L (vs <0.2mg/L), and the odds of residuals being >2.0mg/L (vs ≤ 2.0mg/L). The small number of samples >2.0mg/L in Zambia led to the use of logistic regression models of the odds of detectable T.Cl and F.Cl (≥0.2mg/L), respectively, over pH categories, time-since-treatment, the two products, and crossover period. Results from statistical tests were considered significant within a probability of 5% ($p \leq 0.05$), and of borderline significance between probabilities of 5-10% ($0.05 < p < 0.1$). Statistical outputs are presented within two significant figures.

4.2.2.2 Qualitative analysis

The methodology adopted for the design, implementation, and analysis of the qualitative research component was based on Green and Thorogood (Green and Thorogood, 2013) and Creswell and Clark (Creswell and Clark, 2007), with additional details from a RAND Corporation training manual specific to FGDs and SSIs (Harrell and Bradley, 2009). This paper only presents a portion of the post-survey qualitative findings, focussing on positive and negative product feedback. The emphasis was on obtaining breadth of information, on assessing majority and minority views, and on whether feedback was confirmatory or deviant to questionnaire findings. A relatively deductive approach was taken, based on framework analysis as outlined in Green and Thorogood (2013). English transcriptions of recorded FGDs and interviews, key observations by a dedicated note-taker present at each session, and field notes were assessed by the lead investigator. Feedback was summarized according to the main concordant and discordant responses, the frequency and popularity of given responses, and representative quotes. Qualitative data was used to expand upon quantitative findings, including in a way that might provide a different and divergent interpretation. Qualitative and quantitative findings were consolidated post-analysis following Creswell and Clark's definition of triangulated designs, and specifically, convergence models (Creswell and Clark, 2007).

4.3 RESULTS

4.3.1 PAKISTAN CASE STUDY

4.3.1.1 Descriptive findings

The community in this country study was situated on the edge of a small rural town surrounded by two industrial sites in Sindh province. Over 60% of households were completely illiterate, and over 75% of children did not attend school. The only formal educational facilities were outside the community. Most households were cattle farmers, small local business owners or employees, and physical labourers. Over 98% of households reported experiencing one or both of the two major floods that affected the entire country in 2010 (Gaurav et al., 2011) and Sindh in 2011 (Haq et al., 2012). The Indus River was the primary water source for all households, pumped and distributed through an informal piped network after storage in a gravity tank. The only pre-treatment step was the filtering of large particles at the inlet in the river, and settling in the storage tank. No other treatment steps were followed. Water was received at the household-level through in-yard taps and a small number of standpipes. Approximately one third of households used a standpipe, over half used an in-yard tap, and the remainder had taps within the household. (See Table D1 Appendix D for tabulated descriptive findings). A nearby factory would provide chlorinated water for free but required a 40-minute round-trip and carrying water in containers, and was only used as an emergency source when community water supplies could not be relied upon.

4.3.1.2 Water samples and chlorine residuals over time and between products

Chlorine in water samples

Reportedly treated water samples were observed in approximately 65% of all household visits (1,159 samples) (Table 4.1). Though sample availability dropped significantly over crossover periods ($p<0.001$) (Table 4.2) the proportion of water samples with detectable total chlorine (or "verifiable use") was high – at least 90% – in both crossover periods, and over 80% of all samples met the minimum F.Cl safety limit (0.2 mg/L). The median T.Cl concentration in all Pureit-treated samples was 2 mg/l (Table 4.3), ranging widely from the lower to the upper detection limits (<0.2 – 5 mg/l), and median F.Cl was 1.1 mg/l (ranging from <0.2 – 5mg/l). PoW values were lower, with median T.Cl of 1mg/l (range: <0.2 – 5mg/l), and F.Cl of 0.8 mg/l (range: <0.2 – 5mg/l) (Table 4.3).

"Effective use", or the proportion of all study visits with F.Cl values within the minimum safety limit dropped over crossover period from 64% to 41% ($p<0.001$) (Table 4.1, Table 4.2). On average, 50-60% of a given households' visits had detectable F.Cl or T.Cl (Table 4.4).

Chlorine residual differences between the two products were highly significant ($p<0.001$) (Table 4.2), with higher T.Cl and F.Cl residuals in Pureit-treated samples. This difference was most pronounced in samples >2.0mg/L, representing 30% of Pureit-treated samples as compared to only 8% of PoW-treated samples) (Table 4.3). Chlorine residual levels did not differ significantly between the two crossover periods for T.Cl ($p=0.34$) and F.Cl ($p=0.097$) categories (Table 4.2). Distributions differed slightly across the four visits of each period, though this was only significant for T.Cl residuals in period 1 ($p=0.011$) (Table 4.2).

Secondary measures

The majority of both products' samples were within the same post-treatment pH category (7-7.5), though a significantly greater minority of Pureit-treated samples (15%) were between pH 8-9, compared to only 4% of PoW-treated samples ($p<0.001$) (Table 4.3, Table 4.2). Other sample-related covariates were highly homogenous. Practically all samples were collected from the safe storage containers provided to households and were well-maintained. Over 95% of water was piped river water, and over 98% of samples were below the turbidity detection limit (Appendix F, Table F1)

Table 4 1: Summary of free and total residual chlorine measures over crossover period and across both products (Pakistan)

MEASUREMENT	DISTRIBUTION (both products combined)		
	Period 1	Period 2	Total
Self reported treatment of samples	77%	52%	65%
n *	899	890	1789
Detectable total chlorine in reportedly treated samples ("verifiable use")	90%	93%	91%
n	695	464	1159
Minimum safe free chlorine in reportedly treated samples	82%	78%	81%
n	695	464	1159
Proportion of all households with safe free chlorine levels ("effective use")	64%	41%	52%
n	899	890	1789
Proportion of all households with detectable total chlorine	70%	49%	59%
n	899	890	1789

** all ns: household visits*

Table 4 2: Univariate and stratified Somer's D hypothesis tests of the difference in total and free chlorine distribution between a) products and crossover periods and b) weekly visits (Pakistan)

A)

<table>
<tr><th rowspan="2">Total chlorine</th><th colspan="3">Crossover period 1</th><th colspan="3">Crossover period 2</th><th colspan="2" rowspan="2">Univariate (UV) and stratified differences in chlorine over crossover period and between products (Somer's D✚)</th></tr>
<tr><th>pureit</th><th>purifier of water</th><th>both products</th><th>pureit</th><th>purifier of water</th><th>both products</th></tr>
<tr><td><0.2 mg/l (%)</td><td>10</td><td>10</td><td>10</td><td>6.7</td><td>7</td><td>6.9</td><td rowspan="4">Product differences (UV)***
Stratified: Phase 1***
Stratified: Phase 2***</td><td rowspan="4">Crossover period differences (UV) °
Stratified: Pureit *
Stratified: Purifier of Water °</td></tr>
<tr><td>0.2-2.0 mg/l (%)</td><td>52</td><td>75</td><td>63</td><td>49</td><td>81</td><td>65</td></tr>
<tr><td>>2.0 mg/l (%)</td><td>38</td><td>15</td><td>27</td><td>44</td><td>12</td><td>28</td></tr>
<tr><td>n ▲</td><td>366</td><td>329</td><td>695</td><td>225</td><td>239</td><td>464</td></tr>
<tr><th rowspan="2">Free chlorine</th><th colspan="3">Crossover period 1</th><th colspan="3">Crossover period 2</th><th colspan="2" rowspan="2">Univariate (UV) and stratified differences in chlorine over crossover period and between products (Somer's D✚)</th></tr>
<tr><th>pureit</th><th>purifier of water</th><th>both products</th><th>pureit</th><th>purifier of water</th><th>both products</th></tr>
<tr><td><0.2 mg/l (%)</td><td>19</td><td>16</td><td>17</td><td>19</td><td>25</td><td>22</td><td rowspan="4">Product differences (UV)***
Stratified: Phase 1***
Stratified: Phase 2***</td><td rowspan="4">Crossover period differences (UV)*
Stratified: Pureit °
Stratified: Purifier of Water **</td></tr>
<tr><td>0.2-2.0 mg/l (%)</td><td>50</td><td>74</td><td>62</td><td>51</td><td>68</td><td>60</td></tr>
<tr><td>>2.0 mg/l (%)</td><td>31</td><td>10</td><td>21</td><td>30</td><td>7</td><td>18</td></tr>
<tr><td>n▲</td><td>366</td><td>329</td><td>695</td><td>225</td><td>239</td><td>464</td></tr>
</table>

B)

Total Chlorine	Weekly visits 1	2	3	4	5	6	7	8	Differences in outcome over all visits and within each crossover period (Somer's D✚)
<0.2 mg/l (%)	5.8	9.9	13	12	6.8	7	8	6	Difference over all visits °
0.2-2.0 mg/l (%)	62	63	66	61	64	66	65	65	Stratified within: Phase 1 **
>2.0 mg/l (%)	32	27	21	27	29	27	27	29	Stratified within: Phase 2°
n▲	191	162	180	162	103	115	113	133	

Free Chlorine	Weekly visits 1	2	3	4	5	6	7	8	Differences in outcome over all visits and within each crossover period (Somer's D✚)
<0.2 mg/l (%)	14	17	19	21	18	23	22	23	Difference over all visits *
0.2-2.0 mg/l (%)	64	63	62	57	63	63	58	57	Stratified within: Phase 1 °
>2.0 mg/l (%)	22	20	19	22	19	13	20	20	Stratified within: Phase 2 °
n▲	191	162	180	162	103	115	113	133	

▲ *household visits*
✚ *Somer's D is a non-parametric ordinal measure of association between two variables that is appropriate for clustered data. Further details can be found in Newson (2002). Exact p-values can be found in Appendix F.*
° non-significant (p≥0.1)
** borderline significance (0.1>p>0.05)*
*** significant (0.05≥p≥0.01)*
*** highly significant (p<0.01)

Table 4 3: : Distribution of chlorine residuals, pH and time-since-treatment between products (Pakistan)

Characteristics	Pureit n=591*	Purifier of Water n=568
Total chlorine (mg/L)		
<0.2 mg/l (nd)	9 %	9%
0.2-2 mg/l	51%	78%
>2.0mg/L	40%	13%
median (range)	2 (<0.2-5)	1 (<0.2-5)
Free chlorine (mg/L)		
<0.2 mg/l (nd)	19%	20%
0.2-2 mg/l	51%	72%
>2.0mg/L	30%	8%
median (range)	1.1 (<0.2-5)	0.8 (<0.2-5)
pH		
7-7.5	85%	96%
8-9	15%	4%
Hours since treatment		
median (range)	4 (1-53)	4 (1-54)

** household visits*

Table 4 4: Distribution of within-household sample frequency over all study visits (Pakistan)

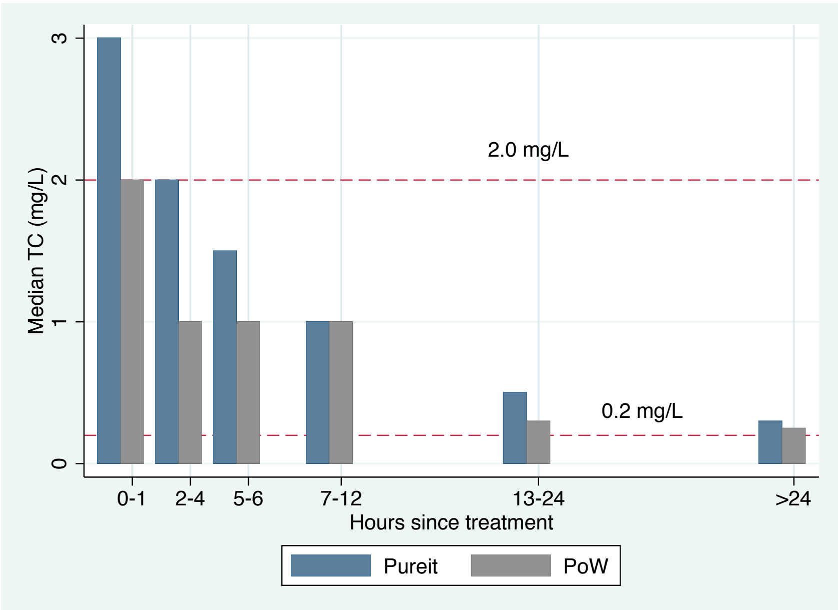
% HH visits with detectable total chlorine		% HH visits with detectable free chlorine	
Categories	%	Categories	%
none	3	none	4
half or less	42	half or less	53
more than half	42	more than half	36
all	13	all	7
n=232 households	median: 63%		median: 50%

4.3.1.3 Trends over reported time-since-treatment

Users of either product reported treating water samples a median of 4 hours prior to visits (Table 4.3). Though samples were only collected if the household claimed to have treated water within 24 hours, approximately 5% of households reported longer treatment times (>24 hours) after enumerators had tested the water and asked for a specific time-since-treatment.

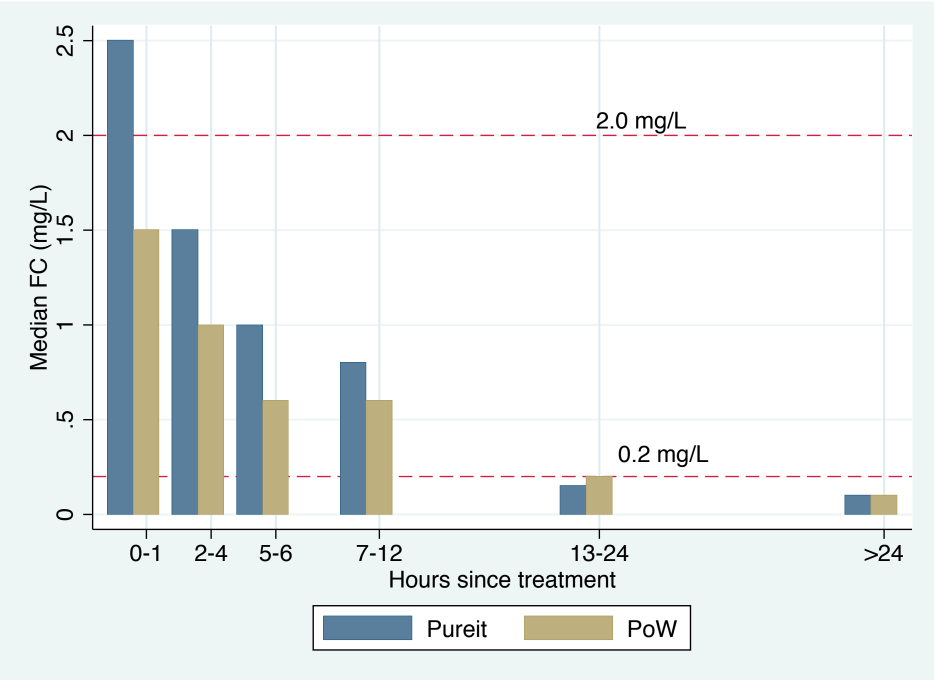
A highly significant reduction was observed in both T.Cl and F.Cl levels across progressive user-reported hours-since-treatment, including after stratifying by product and study period ($p<0.001$, Table 4.2). Figures 4.1 (T.Cl) and 4.2 (F.Cl) illustrate this decrease over categories of time-since-treatment, as well as clear product differences. Pureit-treated samples initially had substantially greater T.Cl and F.Cl residuals than PoW for the first 12 hours since treatment (including median values above 2.0mg/L in the first hour), after which the two products' residual values converged. The products reached the detectable limit within the same amount of time, however. Average T.Cl values for both products were well above the detection limit (0.2mg/L) for samples treated within 12 hours since treatment, and approached the limit in samples treated beyond 24 hours prior to testing. Average F.Cl values were above our safety limit (F.Cl ≥0.2 mg/L) for samples treated within 12 hours previously, crossing below thereafter. A wide range of residual values was observed across all time categories (from <0.2 – 5mg/L T.Cl and F.Cl), as indicated in Appendix F (Table F3 presenting median values and ranges of residuals over time-since-treatment, as well as the proportion of non-detectable values in each category.)

Figure 4 1: Median total chlorine over reported time-since-treatment for Pureit and the Purifier of Water (Pakistan) *



Median chlorine residuals are presented within categories of hours-since-treatment. The x-axis data points are the mid-point of each category in order to present an accurate scale.

Figure 4 2: Median free chlorine over reported time-since-treatment for Pureit and the Purifier of Water (Pakistan) *



Median chlorine residuals are presented within categories of hours-since-treatment. The x-axis data points are the mid-point of each category in order to present an accurate scale.

4.3.1.4 Regression findings

Our main regression findings are stratified by product (Pureit: Table 4.5 a-b; PoW Table 4.6 a-b), as significant interactions were observed between product allocation and crossover period (Wald's $p<0.0001$ for the interaction term), as well as product and pH categories ($p<0.01$) for both T.Cl and F.Cl models *(data not shown)*. Regression estimates underlined the strong reduction in T.Cl and F.Cl over time-since-treatment categories. They also provided some evidence for higher residuals at the higher pH category (8-9), though these were associated with the widest confidence intervals of each model.

Table 4 5: Generalized ordered logistic regression estimates for the odds of a) total chlorine residuals and b) free chlorine residuals ≥0.2 and >2.0 mg/L in Pureit (Pakistan)*

a) Pureit (Total Chlorine)	Predictor categories (% distribution)	Odds of detectable total chlorine (≥0.2mg/L)			Odds of total chlorine >2.0 mg/L			Adjusted Wald's test
	n**=195	OR	95% CI	p-value	OR	95% CI	p-value	p-value
Crossover period	1 (50%)	1			1			
	2 (50%)	1.6	0.81-3.1	0.18	1.6	1.1-2.4	0.016	0.047
pH	<8 (90%)							
	8-9 (10%)	0.65	0.3-1.4	0.27	2.3	1.3-4	0.003	0.0001
Time since treatment categories	0-1 (10%)							
	2-4 (44%)	0.45	0.1-2	0.29	0.4	0.23-0.7	0.001	<0.0001
	5-12 (36%)	0.36	0.08-1.7	0.19	0.18	0.1-0.3	<0.001	
	>12 (10%)	0.18	0.03-0.91	0.039	0.04	0.017-0.12	<0.001	

b) Pureit (Free Chlorine)	Predictor categories (% distribution)	Odds of detectable free chlorine (≥0.2mg/L)			Odds of free chlorine >2.0 mg/L			Adjusted Wald's test
	n**=195	OR	95% CI	p-value	OR	95% CI	p-value	p-value
Crossover period	1 (50%)	1			1			
	2 (50%)	1.1	0.66-1.9	0.69	1.2	0.82-1.7	0.37	0.66
pH	<8 (90%)	1			1			
	8-9 (10%)	0.64	0.32-1.3	0.2	3.2	1.9-5.4	<0.001	<0.0001
Time since treatment categories	0-1 (10%)	1			1			
	2-4 (44%)	0.43	0.13-1.5	0.18	0.43	0.25-0.76	0.004	<0.0001
	5-12 (36%)	0.21	0.064-0.7	0.011	0.22	0.12-0.38	<0.001	
	>12 (10%)	0.046	0.013-0.16	<0.001	0.06	0.03-0.17	<0.001	

**Generalized ordered logistic regression for a predictor variable with 3 categories A,B,C presents two coefficients: the odds of being in category B or C vs A, and the odds of being in category C vs A&B. This can be seen for each predictor variable by reading across the row.*

***n=individual households*

Table 4 6: Generalized ordered logistic regression estimates for the odds of a) total chlorine residuals and b) free chlorine residuals ≥0.2 and >2.0 mg/L in the Purifier of Water (Pakistan)*

a) Purifier of Water (Total Chlorine)	Predictor categories (% distribution)	Odds of detectable total chlorine (≥0.2mg/L)			Odds of total chlorine >2.0 mg/L			Adjusted Wald's test
	n**=197	OR	95% CI	p-value	OR	95% CI	p-value	p-value
Crossover period	1 (50%)	1			1			
	2 (50%)	1.4	0.72-2.7	0.31	0.78	0.47-1.3	0.34	0.32
pH	<8 (90%)	1			1			
	8-9 (10%)	1.34	0.27-6.7	0.72	8.2	3.3-21	<0.001	<0.0001
Time since treatment categories	0-1 (10%)	1			1			
	2-4 (44%)	0.73	0.16-3.5	0.7	0.43	0.22-0.86	0.017	0.0001
	5-12 (36%)	0.32	0.07-1.4	0.13	0.33	0.16-0.68	0.003	
	>12 (10%)	0.13	0.03-0.59	0.008	0.12	0.03-0.5	0.004	

b) Purifier of Water (Free Chlorine)	Predictor categories (% distribution)	Odds of detectable free chlorine (≥0.2mg/L)			Odds of free chlorine >2.0 mg/L			Adjusted Wald's test
	n**=197	OR	95% CI	p-value	OR	95% CI	p-value	p-value
Crossover period	1 (50%)	1			1			
	2 (50%)	0.55	0.34-0.88	0.014	0.62	0.32-1.2	0.14	0.02
pH	<8 (90%)	1			1			
	8-9 (10%)	1.1	0.33-3.6	0.88	10	3.8-27	<0.001	<0.0001
Time since treatment categories	0-1 (10%)	1			1			
	2-4 (44%)	0.25	0.059-1.08	0.063	0.29	0.13-0.66	0.003	<0.0001
	5-12 (36%)	0.13	0.031-0.59	0.008	0.28	0.12-0.62	0.002	
	>12 (10%)	0.03	0.007-0.15	<0.001	0.041	0.004-0.39	0.006	

**Generalized ordered logistic regression for a predictor variable with 3 categories A,B,C presents two coefficients: the odds of being in category B or C vs A, and the odds of being in category C vs A&B. This can be seen for each predictor variable by reading across the row.*
***n=individual households*

4.3.1.5 Product feedback and qualitative findings

This section summarizes product feedback from the survey and outlines key qualitative findings related to field performance. Quotation marks indicate representative quotes from FGDs and SSIs.

Product-related issues (field observations and qualitative feedback)

The study was marked by three issues related to the products and one to the principal water source (further detailed in Appendix E).

- Approximately 10% of sachets were found to have small perforations because packaging was sensitive to handling. This led to higher than expected chlorine residuals (registered as high as 5mg/L for periods as long as 24 hours), which caused concern to several community members (approximately one fifth of the study population), and perceived health issues in a minority of cases. Activities were halted after the second follow-up visit for a few days to investigate the matter, and clarifications were obtained from the manufacturers. After evaluating concerns with all project stakeholders, it was considered safe to continue the study subject to the community's willingness. These issues were addressed through community discussions, held in each study neighbourhood, aimed at clarifying and addressing observed issues, as well as assuaging concerns that were incorrectly associated to the products. Households were given the option to stop the study, or continue using sachets after the team replaced all perforated sachets. The latter was opted for and the study resumed with no further related issues.
- Complaints about "yellow water" were common in the beginning of the study. Upon inspection by the team, it transpired that this was due to households insufficiently stirring sachet contents, leading to some of the sachet powder remaining suspended in the water.
- On four occasions towards the final week of the study, groups of households found that water treated with either product would not fully flocculate or coagulate, remaining unsettled in the buckets.
  - The primary water was also compromised during this time, as the river was being cleaned, leading to irregular moments (lasting up to 24 hours) where water was low in quantity, high in turbidity, and gave off a strong and unpalatable smell. Households would not use the sachets on such occasions, and travel to a nearby factory to obtain free pre-treated water.

Product feedback

Table 4.7 outlines key product feedback information collected in the survey. Households performed well during product mock demonstrations conducted at the end of each study period (where all the steps were enacted without actual treatment, to save time). Households could readily list all steps, including the appropriate treatment time. By the end of the study, 52% of households stated preferring PoW, 39% preferred Pureit and the remainder liked both equally. The distribution of responses was nearly identical across products in most areas, though PoW was most appreciated for taste and general quality, while Pureit's shorter treatment time was appreciated. Households appeared reticent to criticize the products in the survey, with the most common response to requests for negative feedback however, was "nothing" (over 40% of responses for Pureit, and over 50% for PoW).

Qualitative findings did not indicate any clear product preference. Similar positive attributes were often used by households to describe either product, most notably taste. Taste and smell were reported as both positive and negative attributes. Noticeable health improvements, particularly general gastrointestinal wellbeing, usually reported as "my stomach feels good" were mentioned for both products, though more so for PoW, often accompanied by mentions of improved digestion, and even greater "hunger". Respondents were more forthcoming with product critiques in qualitative findings. Puriet's stronger taste was noted by a majority, and though it was more frequently cited as a negative aspect, households who preferred Pureit tended to appreciate the stronger taste. PoW's longer treatment time, and the associated effort, was noted to be a key issue, and more households complained about PoW's smell. Pureit-treated water was said to keep less well over time, with many households reporting that Pureit treated water became bitter overnight; "we cannot store water of Pureit more than 24 hours, the taste of water of Pureit is bitter". A minority of households complained that the powder in both products' sachets would irritate their nose and throat when opened, and Pureit did not open or release its contents easily due to its split packaging (see Appendix E). Enumerators often found households treating water sub-optimally, most notably not stirring the product for long enough. In addition, several households noted purposely changing the instructions, including increasing the volume of water and leaving buckets uncovered for hours to "improve" the taste.

The reported negative health effects of improperly sealed Pureit packets were mostly related to throat and stomach pain. "Many people got abdominal and throat pain when they drank Pureit treated water." However, households that had reported health issues due to Pureit's packaging mostly noted that the issue had been largely resolved after the project team's community discussion: "its been fine since then [referring to community discussion]". Some households also noted that the reported negative health issues in the first crossover period may have been improperly associated to the products: "it doesn't mean that it happens because of products, we already have many health issues".

Table 4 7: Stratified (a) and unstratified (b) product feedback

a) STRATIFIED FINDINGS

CHARACTERISTIC	PRODUCT			
	PUREIT	%	Purifier of Water	%
Single best aspect of product n=219	nothing	7	nothing	5
	taste	23	taste	34
	time	8	how cleans	24
	how cleans	27	general quality	13
	general quality	12	other	24
	other	23		
Single worst aspect of product n=219	nothing	44	nothing	55
	taste	27	taste	8
	smell	21	smell	21
	other	8	time	5
			other	11
	CROSSOVER PERIOD			
	PERIOD 1		PERIOD 2	
Positive aspects of treated water ** (n=220)	general safety	23%	general safety	17%
	safety disease	54%	safety disease	25%
	cleanliness	27%	cleanliness	35%
	looks clear	85%	looks clear	81%
	looks safe	25%	looks safe	30%
	smell	5%	smell	18%
	taste	14%	taste	21%
	like bottled	20%	like bottled	12%
	other	5%	other	
Negative aspects of treated water **	(n=157)			(n=102)
	smell	61%	smell	35%
	taste	32%	taste	18%
	nothing	29%	nothing	53%

b) UNSTRATIFIED FINDINGS

CHARACTERISTIC	DISTRIBUTION
Product preference	
(n=219)	39%
Pureit	52%
Purifier of Water	9%
Equal	
Product rating out of 10	
(n=219)	
Pureit	6 (0-10)
Purifier of Water	5 (0-10)
Product usage demonstration	
(n=222)	
perfect	55%
less than perfect	45%

*** questions with the option to respond with multiple answers. Percentages represent proportion of respondents, and do not add up to 100%*

4.3.2 ZAMBIA CASE STUDY

4.3.2.1 Descriptive findings

This study took place in a low-income settlement in Lusaka, with over 100,000 inhabitants (Chilufya, 2013). Follow-up visits took place between October - December 2012, which included the end of the hot season and the onset of the rainy season. The site is a well-documented low-income area in Lusaka, with a history of inadequate sanitation, water, solid waste management, and endemic, seasonal cholera outbreaks during the rainy season (Chilufya, 2013; Grönwall, 2011). However, only a few days of rainfall took place towards the final visit of this study, and no cholera cases were reported. The primary water source for over 90% of households was public standpipes, set up within the memory of most adult household members and run by the Lusaka Water and Sewerage Company for a monthly fee (UNOSSC, 2005). However, the local environmental health officer had never found detectable chlorine at the standpipes' tap-level, and noted that the pipelines were subject to sporadic contamination, particularly in the rainy season *(C.Nkunka, District Environmental Health Office, personal communication*). This study did not find detectable total chlorine in all major standpipes in the target area (three tests of n=20 standpipes, *data not shown*). Shallow wells accounted for the main secondary water source, and were used regularly by households, mostly for washing, cleaning, and cooking, though also for supplementary drinking-water (Grönwall, 2011). Full adult literacy was observed in over 60% of households. Over 25% of households with children had enrolled all of them in school, and over 50% had half of more of their children in school. Professionally, over 60% of households identified themselves within the middle-level service sector, mostly related to small local businesses. Over 65% of households only had one breadwinner, and over 10% had no steady income. (See Table D2 in Appendix D for tabulated descriptive findings).

4.3.2.2 Water samples over time and between products

Chlorine in water samples

Drinking-water (treated or not[2]) was available on the premises during 94% of all household visits, though samples were only reportedly treated in over 50% of visits (764 samples), decreasing slightly over crossover period from over 53% - 47% (p=0.004) (Table 4.8, Table 4.9). Furthermore, detectable T.Cl residuals were observed in 59% of reportedly treated samples (i.e "verifiable" use), moderately increasing over crossover period from 56 - 63% (p=0.049(Table 4.8, Table 4.9).). Approximately 30%

[2] The presence of any water available during household visits (treated or not) was only collected in Zambia. It was not included in the final Pakistan dataset due to an error in data collection.

of all household visits in the study population had water samples with detectable T.Cl. The proportion of all household visits within the F.Cl safety minimum ("effective use") was between 22 – 24% over the two crossover periods. The majority of households had detectable T.Cl or F.Cl during half or less of their visits.

Median T.Cl values in all samples approached – and F.Cl values reached – the detection limit in Pureit-treated samples (T.Cl 0.3, F.Cl 0.2 mg/l) (Table 4.10). Only median T.Cl values were within the detectable limit for PoW-treated samples (T.Cl 0.2mg/l), while median F.Cl levels were below (F.Cl <0.2mg/l). T.Cl and F.Cl residuals in Pureit-treated samples varied between the lower and upper detection limits (<0.2 - 5 mg/l), and PoW-treated samples between <0.2 - 4 mg/l (T.Cl) and <0.2 – 3.5 mg/l (F.Cl) (Table 4.10). Though average residual differences were slight between the two products, the overall residual distributions were significantly different ($p<0.001$, Table 4.9). Residual levels increased over crossover period Table (4.8). This was mainly due to the greater proportional increase in PoW-treated samples, while Pureit samples did not rise significantly, though maintaining higher absolute residual levels. On two occasions, chlorine residual distributions differed significantly across visits within crossover periods: T.Cl categories in the second month ($p=0.032$), and F.Cl categories in the first ($p=0.04$) (Table 4.8). On average, households had samples with detectable T.Cl during 25% of their visits, and F.Cl ≥ 0.2mg/L during 17% of visits (Table 4.11).

Secondary measures

Samples differed considerably in post-treatment pH levels based on which product was used (Table 4.10), with the majority of Pureit samples tested between pH 8 - 9 (61%) – over 95% of which was at pH 8 – and the majority of PoW-treated samples between pH 7-7.5 (65%). Sample related covariates were homogenous and could not be used in stratified analysis. Over 94% of all collected treated water samples were obtained from the safe storage containers provided in this study, and over 99% of samples were provided without hand contact (all containers had taps attached). No samples were found with turbidity levels above 5 TU, and 95% of containers were in "good" condition (Appendix F Table F2).

Table 4 8: Summary of total and free residual chlorine measures over crossover period and across both products (Zambia)

CHARACTERISTIC	BOTH PRODUCTS		
	Period 1	Period 2	Total
Availability of water	96%	93%	95%
n *	810	791	1,601
Self reported treatment of samples	54%	47%	50%
n	780	734	1514
Detectable Cl in reportedly treated samples ("verifiable use")	56%	63%	59%
n	419	345	764
Minimum safe free chlorine in reportedly treated samples	42%	52%	46%
n	419	345	764
Proportion of all households with safe free chlorine levels ("effective use")	22%	24%	23%
n	780	734	1514
Proportion of all households with detectable total chlorine	30%	30%	30%
n	780	734	1514

Table 4 9: Univariate and stratified Somer's D* tests of differences in total and free chlorine distribution between a) products and crossover periods and b) weekly visits (Zambia)

A)

Total chlorine	Crossover period 1			Crossover period 2			Univariate (UV) and stratified differences in chlorine over crossover period and between products (Somer's D✚)	
	pureit	purifier of water	both products	pureit	purifier of water	both products		
<0.2 mg/l (%)	37	51	44	34	40	37	Product differences (UV) ***	Crossover period differences (UV)**
0.2-2.0 mg/l (%)	49	48	48	46	56	51	Stratified: Phase 1***	Stratified: Pureit °
>2.0 mg/l (%)	14	1	7.2	20	4	12	Stratified: Phase 2**	Stratified: Purifier of Water **
n	197	222	419	174	171	345		
Free chlorine	**Crossover period 1**			**Crossover period 2**			**Univariate (UV) and stratified differences in chlorine over crossover period and between products (Somer's D+)**	
	pureit	purifier of water	both products	pureit	purifier of water	both products		
<0.2 mg/l (%)	53	63	58	43	53	48	Product differences (UV) ***	Crossover period differences (UV)***
0.2-2.0 mg/l (%)	38	37	37	42	46	44	Stratified: Phase 1 **	Stratified: Pureit **
>2.0 mg/l (%)	8.6	0	5	15	1	8.1	Stratified: Phase 2 ***	Stratified: Purifier of Water *
n	197	222	419	174	171	345		

B)

Total Chlorine	Weekly visits 1	2	3	4	5	6	7	8	Differences in outcome over all visits and within each crossover period (Somer's D✚)
<0.2 mg/l (%)	50	41	43	43	33	33	34	50	Difference over all visits *
0.2-2.0 mg/l (%)	44	51	51	47	52	56	53	42	Stratified within: Phase 1 °
>2.0 mg/l (%)	5.8	7.6	5.9	10	15	11	13	8.3	Stratified within: Phase 2 **
n	120	119	101	79	130	75	68	72	

Free Chlorine	Weekly visits 1	2	3	4	5	6	7	8	Differences in outcome over all visits and within each crossover period (Somer's D✚)
<0.2 mg/l (%)	67	55	55	54	46	44	46	58	Difference over all visits **
0.2-2.0 mg/l (%)	32	39	41	41	43	49	47	36	Stratified within: Phase 1 °
>2.0 mg/l (%)	1.7	5.9	4	5	11	6.7	7.4	5.6	Stratified within: Phase 2 ***
n	120	119	101	79	130	75	68	72	

✚ *Somer's D is a non-parametric ordinal measure of association between two variables that is appropriate for clustered data. Further details can be found in Newson (2002). Exact p-values can be found in Appendix F.*

° non-significant ($p \geq 0.1$)

** borderline significance ($0.1 > p > 0.05$)*

*** significant ($0.05 \geq p \geq 0.01$)*

*** highly significant ($p < 0.01$)

Table 4 10: Distribution of chlorine residuals, pH and time-since-treatment between products (Zambia)

Characteristics	Pureit n=371	Purifier of Water n=393
Total chlorine (mg/L)		
<0.2 mg/l (nd)	36%	46%
0.2-2 mg/l	47%	52%
>2.0mg/L	17%	2%
median (range)	0.3 (<0.2-5)	0.2 (<0.2-4)
Free chlorine (mg/L)		
<0.2 mg/l (nd)	48%	58%
0.2-2 mg/l	40%	40%
>2.0mg/L	12%	1%
median (range)	0.2 (<0.2-5)	<0.2 (<0.2-3.5)
pH		
7-7.5	39%	65%
8-9	61%	35%
Hours since treatment		
median (range)	7 (<1-75)	7 (<1-72)

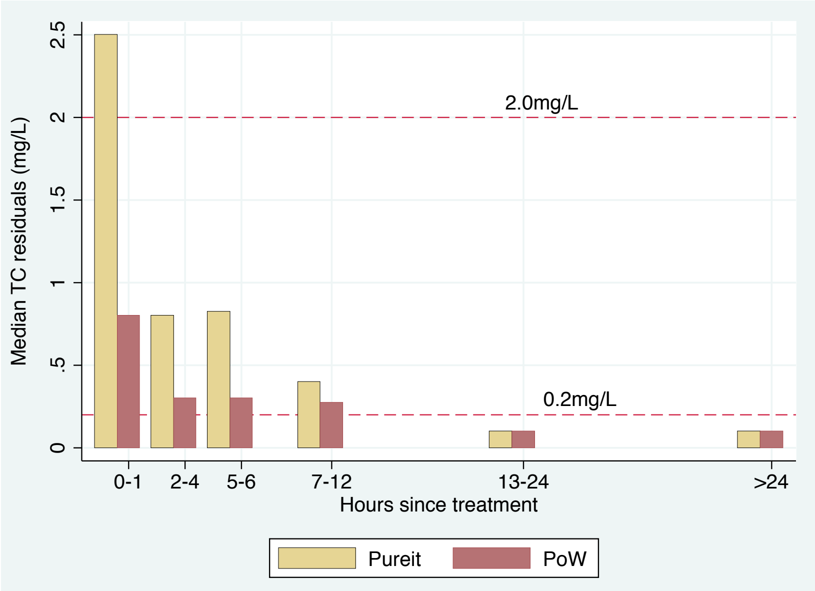
Table 4 11: Distribution of within-household sample frequency over all study visits (Zambia)

% HH visits with detectable total chlorine		% HH visits with detectable free chlorine	
Categories	%	Categories	%
none	16	none	27
half or less	71	half or less	63
more than half	12	more than half	9
all	1	all	1
n=204 households	median: 25%		median: 17%

4.3.2.3 Trends over reported time-since-treatment

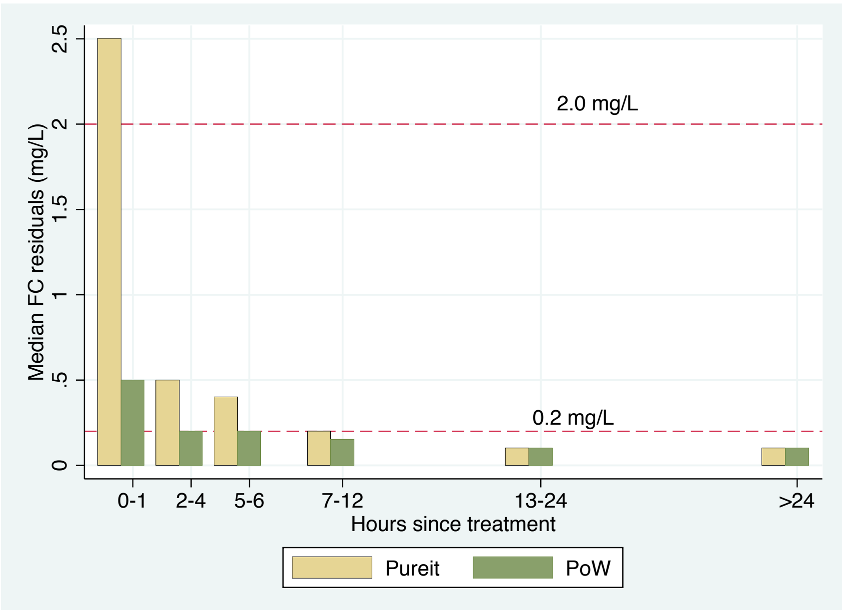
Both products were treated a median of 7 hours prior to the visit (Table 4.10). Figures 4.3 and 4.4 illustrate a clear decrease in residuals over time-since-treatment and product differences. Pureit-treated samples were initially higher than PoW-samples, and subsequently converged, dropping sharply between the first and second hours since treatment. The products reached the detectable limit within the same amount of time. Detectable T.Cl residuals were not observed in samples treated by either product after 12 hours since-treatment. Average F.Cl levels for both products were only longer within the safety F.Cl limit for the first 6 hours since-treatment. Appendix F (Table F4) presents median values and ranges of residuals over time-since-treatment, as well as the proportion of non-detectable values in each category.

Figure 4 3: Median total chlorine over reported time-since-treatment for Pureit and the Purifier of Water (Zambia) *



*Median chlorine residuals are presented within categories of hours-since-treatment. The x-axis data points are the mid-point of each category in order to present an accurate scale.

Figure 4 4: Median free chlorine over reported time-since-treatment for Pureit and the Purifier of Water (Zambia) *



*Median chlorine residuals are presented within categories of hours-since-treatment. The x-axis data points are the mid-point of each category in order to present an accurate scale.

4.3.2.4 Regression findings

Our three-category outcome was collapsed to binary given the low proportion of PoW samples above 2.0mg/L (1-2% of all samples), resulting in multivariate logistic regression models being used to assess the odds of detectable T.Cl and F.Cl (≥0.2-mg/L). The four parameters examined were product, pH, crossover period, and time-since-treatment. Findings are stratified by product as borderline evidence was found of interaction between product allocation and crossover period for detectable T.Cl (interaction term Wald's $p=0.095$), and between product allocation and pH categories for both T.Cl and F.Cl (interaction term Wald's $p<0.001$) (*data not shown*).

Table 4.12 summarizes stratified findings for Pureit, and Table 4.13 summarizes those for PoW. Pureit ($p=0.022$) and PoW ($p=0.006$) had more than twice the odds of detectable F.Cl in the second month of the study. PoW-treated samples had nearly three times the odds of detectable T.Cl in the second crossover period ($p=0.001$), though Pureit samples did not change significantly ($p=0.31$). Pureit-treated samples had greater odds of higher detectable T.Cl at pH values between 8-9 (relative to pH 7-7.5), while PoW samples had lower odds for both detectable T.Cl ($p<0.001$) and F.Cl ($p<0.001$). Both products were associated with similar and clear decreases in the odds of detectable chlorine over categories of time-since-treatment. As interaction was only of borderline significance, we also assessed the full model without stratifying by product, indicating that PoW had approximately half the odds of detectable T.Cl ($p=0.001$) and F.Cl ($p<0.001$) than Pureit (Appendix F Tables F7-8).

Table 4 12 Logistic regression estimates for the odds of detectable total and free residual chlorine across key parameters in Pureit (Zambia)*

Pureit	Predictor categories (% distribution)	Total Chlorine			Adjusted Wald's test	Free Chlorine			Adjusted Wald's test
	n=167	OR	95% CI	p-value	p-value	OR	95% CI	p-value	p-value
Crossover period	1 (50%)	1				1			
	2 (50%)	1.3	0.77-2.2	0.31	**	2.05	1.1-3.8	0.022	**
pH	7-7.5 (53%)	1				1			
	8-9 (47%)	2	1.2-3.5	0.009	**	1.35	0.78-2.4	0.28	**
Time since treatment categories	0-1 (11%)	1				1			
	2-4 (26%)	0.45	0.13-1.5	0.2		0.37	0.12-1.1	0.076	
	5-12 (19%)	0.4	0.11-1.4	0.16		0.32	0.11-0.98	0.046	
	>12 (44%)	0.05	0.016-0.17	<0.001	<0.0001	0.031	0.01-0.09	<0.001	<0.0001

** Total and free chlorine estimates represent separate models, respectively*

*** Adjusted Wald's test only for variables with more than two categories*

Table 4 13: Logistic regression estimates for the odds of detectable total and free residual chlorine across key parameters in the Purifier of Water (Zambia)*

Purifier of Water	Predictor categories (% distribution)	Total Chlorine			Adjusted Wald's test	Free Chlorine			Adjusted Wald's test
	n=171	OR	95% CI	p-value	p-value	OR	95% CI	p-value	p-value
Crossover period	1 (50%)	1				1			
	2 (50%)	2.9	1.5-5.3	0.001	**	2.4	1.3-4.4	0.006	**
pH	7-7.5 (53%)	1				1			
	8-9 (47%)	0.3	0.16-0.55	<0.001	**	0.17	0.08-0.34	<0.001	**
Time since treatment categories	0-1 (11%)	1				1			
	2-4 (26%)	0.32	0.09-1.08	0.065		0.3	0.12-0.76	0.011	
	5-12 (19%)	0.23	0.06-0.89	0.034		0.2	0.07-0.59	0.003	
	>12 (44%)	0.02	0.006-0.072	<0.001	<0.0001	0.015	0.005-0.041	<0.001	<0.0001

** Total and free chlorine estimates represent separate models, respectively*

*** Adjusted Wald's test only for variables with more than two categories*

4.3.2.5 Product feedback and qualitative findings

Table 4.14 summarizes product feedback questions covered in the survey. Households performed relatively well during mock demonstrations conducted at the end of each month, and an improvement was observed in the second crossover period. Approximately 58% of respondents stated preferring PoW, 27% Pureit, and the remaining 15% liked both equally. An overall preference for PoW is observed in product ratings and general feedback. However, similar factors were used to describe both products' attributes. The most common positive factors included the physical appearance of water and safety, followed by taste and smell. The most common negative attributes were taste and smell (more frequently mentioned for Pureit), and complexity of usage and time taken (mostly related to PoW). PoW was preferred for its taste, and Pureit for the shorter stirring time needed (2 as opposed to 5 minutes). Coagulation and flocculation issues were also reported for both products, though more so for Pureit.

Qualitative feedback supported the key product attributes observed in survey data. Responses did not indicate a clear product preference however. Attributes such as taste were discussed as equally positive and negative factors and households who preferred the stronger-tasting Pureit often sought its distinctive taste out ("I can taste it and know the difference [between]…the tap and…treated [water]"). Treated water was widely reported as tasting like "mineral water" (i.e bottled store bought water). Other additional information obtained from qualitative findings included the fact that a few households noted Pureit's taste remaining for longer than that of PoW (up to three days according to one respondent). A significant minority of households noted that when Pureit sachets were opened, it could act as a throat or nose irritant ("I want to know why the powder gets to the nose"). A minority of respondents noted that Pureit coagulated poorly at times. PoW on the other hand was noted by a similar proportion as staining the white sieving cloth more easily than Pureit. Concerns were raised by a minority of households regarding Pureit's packaging being split in two sections, with some of the powder not always releasing properly into the water. A minority of respondents described feeling unwell, or having their children dislike the products, and only continued using the products for non-drinking purposes (cooking, cleaning). Some households also found that the ill effects wore off and continued their usage. The challenge in following all treatment steps, particularly the longer stirring time of PoW samples was commonly mentioned, and observed by enumerators who frequently provided users with guidance during visits.

Table 4 14: Stratified (a) and unstratified (b) product feedback*

a) STRATIFIED FINDINGS				
	PRODUCT			
CHARACTERISTIC	PUREIT	%	Purifier of Water	%
Single best aspect of product n=198	taste	37%	taste	69%
	smell	11%	smell	7%
	time taken	11%	how cleans	6%
	how well cleans	15%	general quality	10%
	general quality of water	18%	health improved	5%
	health	7%		
	nothing	14%		
Single worst aspect of product n=198	taste	15%	smell	5%
	smell	33%	time taken	54%
	bad coagulation	24%	complexity	8%
	nothing	16%	nothing	5%
Positive aspects of treated water **	safety in general	45%	safety in general	34%
n=198	safety from disease	33%	safety from disease	39%
	cleanliness	42%	cleanliness	39%
	water looks clear	29%	water looks clear	36%
	water looks safe	21%	water looks safe	29%
	water smells better	21%	water smells better	35%
	water tastes better	37%	water tastes better	52%
	like mineral/bottled water	9%	like mineral/bottled water	29%
	other		other	
Negative aspects of treated water **	smell	57%	smell	27%
	taste	40%	taste	24%
n=198	complexity		complexity	25%
	treatment time	10%	treatment time	18%
	smell/taste/irritation when opening packet	10%	smell/taste/irritation when opening packet	29%
	issue with coagulation/settling at times	13%	issue with coagulation/settling at times	10%
	nothing wrong	40%	nothing wrong	75%
	CROSSOVER PERIOD			
Product mock demonstration rating n=198	PERIOD 1		PERIOD 2	
	perfect	57%	perfect	75%
	less than perfect	43%	less than perfect	25%

**n= households ** questions with the option to respond with multiple answers. Percentages represent proportion of respondents, and do not add up to 100%*

Table 4.14 b)

b) UNSTRATIFIED FINDINGS	
CHARACTERISTIC	DISTRIBUTION
Product preference (n=198)	
Pureit	27%
Purifier of Water	58%
Equal	15%
Product rating out of 10 (n=197)	
Pureit	7.5 (1-10)
Purifier of Water	10 (1-10)
Most important reasons for treatment (n=222)	
taste	36%
general quality of water	17%
health improved	37%
other	10%

4.4 DISCUSSION:

4.4.1 Key findings

Our multisite comparative study of Pureit and PoW's field performance found noteworthy differences in field performance between the two products, between study sites, and over time. It raises concerns about Pureit's field performance and adds to the evidence base on POU effectiveness monitoring and evaluation methods. The median free chlorine residual level in all samples was 1.1 and 0.8 mg/l for Pureit and PoW in Pakistan, respectively, and 0.3 and 0.2 mg/l for Pureit and PoW in Zambia, respectively. "Effective use" measures suggested that over half of all study visits in Pakistan, and less than a quarter in Zambia included water that was "safe", within minimum WHO and CDC guideline values (CDC, 2000; WHO, 2011). Pureit-treated samples had higher residual levels in both country studies, while each product's residual profile differed significantly between the two countries. Water treated with either product in Pakistan was safe from recontamination for the first 12 hours since user-reported treatment, meeting WHO (0.2mg/) and SPHERE guidelines (0.5 mg/L) for point-of-delivery water treatment (Sphere Project, 2011; WHO, 2011), though failing to meet CDC guidelines requiring 0.2mg/L F.Cl concentrations for up to 24 hours(CDC, 2000). In Zambia both products delivered safe water for the first 6 hours since treatment, which would be considered unacceptable according to CDC, WHO and SPHERE guidelines (CDC, 2000; Sphere Project, 2011; WHO, 2011). Qualitative feedback gave critical insight into field performance that were not covered by water quality measures, most notably in Pureit's packaging issues in Pakistan, and reported issues in coagulation and flocculation for both products in both countries. Pureit's key benefit is shorter treatment time and simpler treatment steps, relative to PoW. Our recommendation to the manufacturer included improving its buffering agent, and improving the robustness of its packaging. We also questioned the need to spike and subsequently quench chlorine residuals, and whether this would improve the taste.

4.4.2 Product differences

We expected Pureit to have overall lower residuals than PoW after the first hour after treatment, based on information from the manufacturer (*R. Venkataraghavan, Hindustan Unilever, personal communication*). Pureit's characteristic mode of action can be observed in our plots of chlorine residuals over time (Figures 4.1-4.4), where initial concentrations were considerably higher than those in PoW-treated samples, but subsequently reduced sharply. This was due to the action of a chlorine-quenching agent (Marois fisset et al. *submitted).* Pureit's developers approximated initial levels to be between 2 - 4 mg/L (F.Cl), dropping to 0.5 mg/L between 2 – 5 hours post-treatment due to the chlorine quenching agent. While specifying that concentrations were subject to different source water conditions, water was intended to be safe to consume for 48 hours if safely stored (*R. Venkataraghavan, Hindustan Unilever , personal communication*). The premise for this method of delivery was efficacious and rapid initial disinfection, followed by more taste-acceptable water thereafter.

However, our findings suggested that Pureit's rate of residual decay was significantly higher than PoW's, particularly within the first 6 hours since reported treatment. Though PoW samples maintained lower residuals than Pureit, the two products still passed the lower threshold of detectable chlorine at the same time in both country studies. Thus PoW-treated samples were no less "safe" or detectable than Pureit samples in both countries. This study was preceded by an efficacy assessment (Marois-Fiset et al., submitted) conducted in controlled laboratory conditions. Marois-Fiset and colleagues also observed Pureit's spiking- and quenching- mode of action, questioned the taste-acceptability based on the higher end of observed residuals, and found chlorine residual decay to vary widely based on source water conditions, with detectable F.Cl ranging from >1 mg/L after 24 hours, to being undetectable within 4 hours (*ibid*).

Average Pureit-treated samples were above 2.0mg F.Cl for at the first hour in both countries, and the range of estimates across all time categories included water at least as high as 5 mg/L (and may have been higher as this was our detection limit). Thus some Pureit-treated samples were above the CDC recommended "taste-acceptability" levels of, and potentially higher than the maximum WHO guideline (WHO, 2011). We hypothesized that Pureit's taste would be perceived to be less noticeable than PoW's and thus more acceptable. Our chlorine residual findings, supported by strong qualitative feedback confirmed that Pureit's taste was considerably stronger than PoW's. However, the stronger taste in well-packaged Pureit sachets did not result in lower acceptability.

Post-treatment pH levels also differed between the two products, with significantly more Pureit-treated samples at pH 8-9 than PoW-samples in both countries, though most significantly in Zambia. These findings suggest a potentially weaker buffering capability in Pureit. Ambient pH is strongly related to chlorine's dissociation in aqueous solution, and may result in less effective disinfectant properties (Edzwald, 2011; WHO, 2011). The WHO drinking-water quality guidelines recommend pH values below 8 (WHO, 2011). Pureit's weaker buffering was also observed in the efficacy study conducted by Marois-Fiset and colleagues, in addition to lower log reduction values of *E. coli* in water sources with pH values above 8 (Marois-Fiset et al., submitted), (ibid). These findings agree with our hypothesised weakness in Pureit's buffering, and may suggest less effective water disinfection.

4.4.3 Variability in effectiveness measures over time and within products

Field performance measures varied substantially over time and between study sites, underlining the dynamic nature of *in situ* POU water quality, and the influence of site- and user-related factors.

Our findings indicated clear shifts in the proportion of samples, and chlorine residual levels between products and over time, most notably over crossover period, indicating that cross-sectional assessment would have led to different conclusions on water quality, including verifiable and effective use based on when measurements were taken. The same products also performed markedly differently across the two country studies, with higher overall residuals observed in Pakistan. Country-level differences in water quality were likely to be accurate representations of differences between sites given that the vast majority of samples in both country studies were obtained under conditions of safe storage and high container maintenance. On balance, the major reason for country level differences may have been lower adherence and greater reporting bias in Zambia. This was suggested by the lower proportion of "verifiable use" in Zambian water samples (60% compared to 90% in Pakistan), and the high proportion of samples with non-detectable findings across all time categories (e.g 50% for samples beyond 12 hours, roughly double the amount seen in Pakistan, *Appendix F Tables F3 and F4*). Furthermore, if source water were behind country differences, our findings would suggest greater chlorine demand in Zambia, where most households relied on standpipe water managed by the municipal authorities, reportedly following standard treatment procedures (*C.Nkunka*, *District Environmental Health Office, personal communication*), as compared to Pakistan where the population relied on pumped river water with little pre-treatment and visible and observed contamination.

4.4.4 Product-related issues and anomalies

Pureit's packaging issues highlight the importance of thorough "real-world" pre-testing of POU products, including parameters such as the user-interface which are not included in regular effectiveness guidelines but nonetheless critical to health impact, effectiveness and adherence. Pureit's value in emergencies and real-world deployment is significantly weakened by its reliance on a quenching agent which is unstable in ambient humidity, and packaging that is easily compromised by normal handling (e.g storing in a container, frequent removal to take out new sachets). Marois-Fiset et al's efficacy assessment also found a subsample of packets with perforated edges, in which the powder had congealed. It was suggested that one or more of the active compounds in the product were hygroscopic and that their function may change after exposure to ambient moisture

(Marois-Fiset et al., submitted), and this was confirmed by the manufacturer during the field trial in Pakistan (*R. Venkataraghavan, Hindustan Unilever personal communication*).

It is unclear what led to the sporadic issues in coagulation and flocculation, reported consistently by a minority of households in both countries and observed by the study team (see Appendix E). Marois-Fiset et al's findings suggest that these might have been due to treatment of colder water (below 5°C) (Marois-Fiset et al., submitted). While issues in both country studies were mostly reported during the onset of the cold season, both studies were conducted in relatively temperate climates, and earlier studies of PoW found high efficacy between 3 - 5°C (Souter et al., 2003). Discussions with the manufacturers of PoW indicated that water aeration may have had a role to play (*A.T Kamphuis, Procter&Gamble, personal communication*), or unexpected and non-characterised sources of contamination, which would be particularly likely in the Pakistan study where most issues were during the annual river cleaning operations (*Appendix E*). Further research into the likelihood of such issues occurring is important for products that need to be robust in turbid and contaminated water sources. An additional field performance issue emerging from the qualitative findings was the complaints and instances of "yellow" water, related to insufficient product stirring. This underlines the practical challenge of using CDPs, as well as the contrast between high scores in "mock" product usage demonstrations and the quality of treatment observed in practice.

4.4.5 Limitations

Though conducted in areas with recent experiences of emergencies, this study's findings do not reflect emergency-level field performance, given the fact that it took place under normal conditions, and included high levels of follow-up and support. The current evidence base suggest that effectiveness and adherence vary widely in emergency contexts, however (Brown et al., 2012), as observed more generally across POU studies (Clasen et al., 2007; Waddington et al., 2009).

This study based itself on simple water quality testing kits as these are commonly employed and represent field-ready methods. Pool test kits and turbidity tubes are relatively inaccurate, and introduce inherent bias in our findings, particularly towards misclassifying chlorine residuals on the detectable limit as being undetectable, and turbidity values above 5 NTU as being on or below the detection limit (Dorea and Simpson, 2011; Murray and Lantagne, 2015).

Courtesy bias may have led to inaccurate report of time since treatment in both countries. While weekly visits were unannounced, households could often tell when enumerators were approaching as they visited nearby households, which may have affected the likelihood of finding treated water on the premises. Source water could have been further tested and characterised investigated to help compare the two country studies and assess differences in chlorine residuals over time. The presence of F.Cl ≥0.2mg/L was used to indicate safety, though it is recognized that in the absence of microbial water quality tests, chlorine-resistant pathogens may have been present in samples that qualified within "effective use", such as protozoan cysts, helminth eggs, or even chlorine-resistant bacteria (Baker et al., 2013; WHO, 2002). While 2.0mg/L was used as the F.Cl residual taste acceptability threshold in this study, as it is within CDC guidelines (CDC, 2000), setting free or total residuals as a benchmark for taste is questionable. Free chlorine may be a poor indicator of "chlorine taste". F.Cl bears little organoleptic properties, while other factors, many of which combine with chlorine byproducts such as chlorophenols and chloramines may be more involved in producing taste and odour (Bruchet et al., 2004; McDonald et al., 2009; Piriou et al., 2004).

4.4.6 Conclusions

This study presents a mixed-methods, multi-measure assessment of field performance, and is the first field evaluation of the Pureit sachet. The version of Pureit that we assessed was not found to be suitable for implementation. Our findings also underline the complexity of measuring effectiveness in POU products. Our results recommend carefully piloting POU products before full-scale implementation, and providing adequate support to the proper usage of the products, particularly CDPs. We recommend that field performance measures use longitudinal assessments and include adherence measures, where possible, as well as qualitative feedback on user experiences. This would help contribute towards better optimizing POU, and compare differences in impact in different studies.

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Chapter 5. Measuring short-term adherence to two point-of-use water treatment methods in Pakistan and Zambia: a longitudinal crossover trial

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SECTION A – Student Details

Student	Ameer Shaheed
Principal Supervisor	Sandy Cairncross
Thesis Title	A field performance and adherence study of point-of-use water treatment in Zambia and Pakistan

If the Research Paper has previously been published please complete Section B, if not please move to Section C

SECTION B – Paper already published

Where was the work published?	N/A		
When was the work published?	N/A		
If the work was published prior to registration for your research degree, give a brief rationale for its inclusion	N/A		
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Where is the work intended to be published?	Environmental Science and Technology, Journal of Water and Health, Am J Trop Med, PLoS One (in order of preference)
Please list the paper's authors in the intended authorship order:	Shaheed A, Bruce J, Bazezew N, Bastable A, Cairncross S, Brown J
Stage of publication	DRAFT

SECTION D – Multi-authored work

For multi-authored work, give full details of your role in the research included in the paper and in the preparation of the paper. (Attach a further sheet if necessary)	I took the lead role in data collection and analysis, as well as in drafting this manuscript

Student Signature: ______________ **Date:** 26/09/15

Supervisor Signature: Sandy Cairncross **Date:** 26/09/15

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ABSTRACT

The health benefits of point-of-use (POU) water treatment can only be realized through high adherence (correct and consistent usage of the methodology over time). We conducted a longitudinal crossover assessment of adherence to two flocculant-disinfectant POU products across more than 200 households in emergency-prone settings in peri-urban Sindh, Pakistan and urban Lusaka, Zambia. A range of measures commonly used in POU studies were collected over eight weekly unannounced visits.

All measures of adherence dropped sharply in the second crossover period, adherence was lower in Zambia than in Pakistan, and no clear difference in adherence was found between exposure to a particular product. Median weekly usage dropped over crossover period from 9 - 5 sachets/household/visit in Pakistan (44%), and 6 - 4 sachets/household/visit in Zambia (33%). Furthermore, over 33% of households in Pakistan and 50% in Zambia also reported consuming untreated water throughout the study, increasing in the second month of the study. On average, 2L of treated water/capita /day was available in Pakistan, and 1.3L in Zambia. Median adherence to SPHERE minimum recommended consumption quantities (2.5 L/capita/day) dropped from 100 – 57% in Pakistan, and from 57 – 44% in Zambia, though this would have been lower if untreated water were included. Furthermore, self-reported measures differed considerably from observed measures. Over 80% of observed values were in higher categories of stated usage in Pakistan, and 65-75% of observed values in Zambia.

The relatively low and decreasing adherence observed in this study suggest that the products would have provided little to no protective effect to the study population, and underline the need to include adherence estimates in POU studies. Our findings also demonstrate the challenges in accurately measuring adherence, suggesting the need to assess compliance longitudinally, to focus on objective as opposed to self-reported measures, and to include untreated water consumption in assessments. Better understanding adherence in this manner may be a critical step towards optimizing POU water treatment interventions.

5.1 INTRODUCTION

The health benefits of improved water-quality interventions are delivered through the sustained avoidance of contaminated water (Cairncross and Valdmanis, 2006). It is estimated that 663 million people lack access to a water source defined as "improved" according to the United Nations Millennium Development Goals (WHO/UNICEF, 2015). This definition does not include water quality however, and as many as 1.8 billion people (Bain et al., 2014) may consume water at risk of faecal contamination. In 2012, inadequate water, sanitation, and hygiene (WASH) practices and facilities led to approximately 842,000 deaths per year, 502,000 of which were due to contaminated water (Prüss-Ustün et al., 2014). Studies of waterborne pathogens and associated health risks suggest that beneficiaries must consume microbiologically and chemically safe drinking-water with very high consistency to enjoy health benefits (Brown and Clasen, 2012; Enger et al., 2013; Hunter et al., 2009). Correct and consistent adoption is particularly important in settings where point-of-use (POU) water treatment methods are the principal means to obtain safe water, given the need for sustained, individual- or household-level behaviour change(Clasen, 2015). However, there is a paucity of data on adherence in the POU evidence base, and the available evidence indicates high variable and often very low adherence (Rosa, 2012). This paper examines adherence in a multi-country assessment of two POU methods in contexts of short-term uptake.

"Adherence", or "compliance" has been defined as the correct and consistent adoption of a POU product(Clasen, 2009), or the total proportion of treated water out of an individual's total water consumption(Brown and Clasen, 2012; Enger et al., 2013). A number of studies have explored the relationship between POU adherence and health outcomes using Quantitative Microbial Risk Assessment (QMRA), modelling probabilities of infection based on dose-response findings in reference pathogens(Brown and Clasen, 2012; Enger et al., 2013; Hunter et al., 2009). Hunter and colleagues found that nearly all of the annual health gains from piped water were lost from only a few days of raw water consumption, and that the risk was highest in young children(Hunter et al., 2009). Brown and Clasen (2012) and Enger and colleagues (2012) examined associations between the consumption of low quality water and disability-adjusted life years (DALYs), finding that even a slight reduction from perfect adherence could lead to drastic increases in risk. Brown and Clasen (2012) found that as much as 96% of predicted health gains were lost from a modest decrease in adherence from 100 – 90%. In the event of imperfect adherence, higher POU efficacy (measured as log reduction values – LRVs – of indicator organisms), were only associated with marginal health improvements. Thus POU interventions may need to result in high fidelity consumption to deliver health benefits, including all sources of water consumed within and outside the household.

Despite their critical role in health impact, adherence estimates vary widely and are missing in much of the evidence base (Waddington et al., 2009). It is very challenging to directly and objectively assess use, given the individual household-level practice needed, the number of possible sources for water consumption, and the fact that treatment needs to be sustained for as long as the method is expected to be used. Improving reporting on adherence has been widely cited as one of the key needs to improve estimates of POU health impact and sustainability, and as a potential explanation for the variability observed in health impact (Arnold and Colford, 2007; Clasen et al., 2007; Eisenberg et al., 2012; Waddington et al., 2009; Wolf et al., 2014). A wide range of measures and analytic methods are employed, with varying degrees of accuracy, no common consensus as to their strengths and limitations, nor a set standard of usage (Clasen, 2009; Schmidt et al., 2011). A review of 30 POU studies found that 7 did not report adherence, 9 only measured it by occasional observation, and none did so as a direct measure (Clasen, 2009). A number of studies focus on intention-to-treat analysis(Jain et al., 2010; Mengistie et al., 2013), and self-reported measures ((Inauen et al., 2013; Lilje et al., 2015; Stocker and Mosler, 2015)), all of which have been found to be considerably prone to bias (Arnold et al., 2009; Colindres et al., 2007; Rosa, 2012). Few studies collect information on usage in a longitudinal manner, which is important as several studies have found that POU is practiced infrequently, often based on perceived need (Olembo et al., 2004; Quick et al., 2002; Reller et al., 2003). Even fewer studies report on whether households supplement their treated water with untreated sources, though this may be commonly practiced in many settings (Bustamante et al., 2004; Rosa et al., 2014; Shaheed et al., 2014). Furthermore, the majority of POU interventions are at the household level, and do not include other sources of drinking-water such as schools, workplaces, or hospitals (WHO, 2014).

The clearest conclusion that can be made about adherence is that it varies widely and is still poorly estimated. Systematic reviews by Arnold and Colford (2007), Clasen and colleagues (2007), Hunter (2009), and Waddington and colleagues (2009) found overall decreases in the health impact of longer duration studies, citing lower adherence with time as a potential explanatory factor. Most reviews found larger reductions in disease in studies reporting higher adherence (Arnold and Colford, 2007; Clasen et al., 2007). One of the main reasons suggested for this decrease over time was “discontinuance” of the POU methods as users perceived costs of usage outweighing benefits (Waddington et al., 2009), decrease in interest, and an increase in user-fatigue (Arnold and Colford, 2007). A number of studies have shown that POU adherence can also be considerably high in certain settings (Chiller et al., 2006; Fiebelkorn et al., 2012; Thevos et al., 2000). The current evidence base makes it is difficult to draw clear conclusions on what adherence to a given intervention may be like, and how high adherence could potentially reach, though it is critical to optimizing interventions as well as assessing the scope and scalability of POU methods(Clasen, 2015). Measures of usage have several applications, including as primary outcomes to explore behaviour change(Mosler et al., 2010), POU product preferences(Luoto et al., 2011), or as covariates for health outcome studies(Brown et al., 2008). Improved adherence estimates would greatly improve the outcome estimates of various studies of POU, including studies of health impact and of behaviour change.

This study assesses adherence to two POU flocculant-disinfectants products (or "coagulant/disinfectant products" – CDPs): Procter & Gamble's Purifier of Water ® and Unilever Ltd.'s Pureit sachet ® (a new product to the market, first field-reviewed in this manuscript). Our objectives were to conduct a detailed assessment of short-term adherence, employing and comparing a range of measures that are commonly employed in field settings. A longitudinal crossover design was conducted in urban Lusaka, Zambia, and peri-urban Sindh, Pakistan. We collected data on observed and self-reported used product sachets, as well as chlorine residuals in reportedly treated water samples over eight unannounced weekly household visits. These measures allowed us to assess trends in used sachets and water consumption over time, as well as the difference between self-reported and observed usage measures.

5.2 METHODOLOGY

5.2.1 Implementation

See Appendix B for an abridged overview of study implementation (excluding qualitative methods) that will be used in the published version of all three results chapters in this thesis, and Chapter 3 for further methodological details.

5.2.2 Data analysis

We employed three principal outcomes: (1) observed used sachets, (2) self-reported daily rates of usage, and (3) the availability and presence of detectable chlorine in user-reported treated water. Data on self-reported concurrent consumption of untreated water was also collected upon every visit, and included as a secondary outcome of interest and a covariate in some of our analysis. In this paper, the word "adherence" refers to sachet usage over time (equivalent to "compliance" in much of the POU literature(Clasen, 2015)), and "usage" refers to sachet usage at a single or over several points in time.

The primary outcome in this study was observed used sachets per visit (i.e approximately weekly usage). Enumerators personally recorded all used and unused sachets upon every weekly visit. Daily usage rates per visit were calculated from weekly measures using the number of days between each repeat visit. Daily rates could be compared to self-reported usage, which was based on the respondent's estimation of daily household sachet usage in the past week. Household size, together with daily rates were used to calculate per capita consumption of safe water. Water samples were collected if reportedly treated by a household member and tested for detectable total (TC) chlorine, used to validate product usage in samples. All usage data and related analysis was clustered across repeat visits within households.

These outcomes were used for three major areas of investigation: 1) sachet usage over time and between products; 2) consumption of treated water; and 3) differences between self-reported and observed outcomes. This was addressed using three major methods: a) hypothesis tests specific to crossover designs (Senn, 2002), b) Somer's D non-parametric analysis of variance, allowing for clustering within households (Newson, 2002), and c) regression models. Crossover-specific tests employed total used sachets per crossover period in 2x2 hypothesis tests assessing differences based on product allocation and the order in which products were received. Somer's D tests used data collected longitudinally over each repeat visit and clustered per household. Different forms of regression were employed, based on the outcome being investigated, including: logistic (for binary outcomes); ordered and generalized ordered logistic (for categorical outcomes); and negative binomial and zero-inflated negative binomial models (for continuous outcomes). Somer's D tests were used to first assess each of these outcomes at a bivariate and stratified level, followed by regression models specific to each. Interactions were tested for in all regression models, and reported if significant differences were found. These methods are further outlined below, with details on the methodology employed by Senn (2002) in Appendix G-1:

<u>*Measures overview*</u>

- *Observed sachet usage*
  - Observed used sachet counts per visit (i.e an approximation of weekly usage) were the primary objective outcome of usage, calculated by subtracting each visits used packets to those of the prior week (except for visit 1 where used packets for that visit were sufficient). Enumerators also kept records of used and unused packets that were missing. Weekly counts per household were assessed using Somer's D analysis, negative binomial regression (in Zambia), and zero-inflated negative binomial regression (in Pakistan).
- *Untreated water consumption*
  - Households were asked if they had also consumed untreated water since the last household visit, and if so, whether it was less, equal or greater than their consumption of treated water. This was assessed as a binary outcome for all analysis (household did or did not consume untreated water since the past visit).
- *Per capita consumption*
  - Per capita consumption was calculated based on household size and a daily estimate of observed usage per visit (dividing usage per visit by the days-between-visit for each household). Estimates of daily per capita consumption in Litres was used to create a categorical outcome assessing the percentage adherence to the minimum safe water consumption guidelines set by SPHERE (Sphere Project, 2011): 2.5 L per capita per day. The categories were <50; 50-90%, >90% adherence to 2.5 L/capita/day of treated water (any values above 2.5L were capped at 100%). Ordered logistic regression used consumption as a categorical outcome with three categories (<50; 50-90%, >90%).
- *Water samples*
  - Water samples served as an indicator of product effectiveness (examined in depth in Chapter 3), and as an objective indicator of reportedly treated water samples by

measuring detectable total chlorine. Water samples could not be used to approximate daily usage as they were collected on a per-visit basis.

- *Observed vs Stated usage*

Observed usage was compared to household's self-reported estimates of their daily usage at each visit. Households were asked to classify their daily usage since the past visit into one of three categories: 0 sachets/day/visit (i.e no usage); <1 sachet/day/visit (e.g 2 every three days); and ≥1 sachet/day/visit (e.g everyday, or more than one a day). Observed usage per visit was transformed to fit within the same three categories. Stated and observed measures were individual assessed using Somer's D analysis, and compared together using logistic models of the odds of ≥1 sachet/day/visit vs <1 sachet/day/visit.

Results from statistical tests were considered significant within a probability of 5% ($p \leq 0.05$), and of borderline significance between probabilities of 5-10% ($0.05 > p \leq 0.1$). The majority of households had data over all eight visits of the study, and a minority either dropped out (5% in Pakistan, 4% in Zambia), or had missing data (10% Pakistan, 6% Zambia). Table 5.1 outlines the different approaches used. Calculations pertinent to adherence over the entire study or crossover periods were only conducted with households that had a complete dataset, while Somer's D tests were able to include data that was missing for some visits.

Table 5 1 Summary of measures and methods

ASSESSMENT	OUTCOME MEASURE	TEST
Sachet usage over time and between products		
Crossover-specific analysis of aggregate sachet differences over crossover period and products (Senn, 2002)	Total used sachets per household per crossover period	T-test / Wilcoxon signed rank test *
Used sachets over time and between products	Used sachets per visit	Somer's D
		Negative binomial regression (Pakistan)
		Zero-inflated negative binomial regression (Zambia) [1]
Consumption of treated water		
Water sample availability over time and between products	Binary availability status of water samples per visit	Somer's D
Detectable chlorine in reportedly treated samples	Binary presence or absence of detectable total chlorine (≥0.2mg/L) in water samples	Somer's D
		Logistic regression
Untreated water use	Reported consumption of untreated water per visit	Descriptive summary, and as a binary variable (use/do not use) in regression models
Per capita consumption of safe water	Litres of treated water per capita per household per visit	Somer's D
	Also presented as % adherence to SPHERE guideline minimum 2.5L /capita/day (<50, 50-90, >90% adherence)	Ordered logistic regression (Zambia)
		Generalized ordered logistic regression (Pakistan)
Differences between self-reported and observed outcomes.		
Observed vs Stated used sachet	Daily usage estimates per household per visit	Somer's D
	Presented as a categorical outcome: 0; <1; ≥1 sachet/day/visit	Generalized ordered logistic regression

** depending on outcome distribution*

[1] *Every outcome for a given independent variable in the zinb models was associated with two components: IRRs for all positive integers (i.e sachet counts ≥1), and odds ratios (ORs) comparing the odds of 0 sachets to ≥1 sachets (i.e. representing the odds of no sachets being used, reported as "non-usage" in this manuscript).*

5.3 RESULTS

5.3.1 PAKISTAN CASE STUDY

5.3.1.1 Descriptive findings

See Section 4.3.1.1 (Chapter 4) and Appendix D (Table D1) for an outline of descriptive findings that will be used in published versions of this chapter.

5.3.1.2 Trends in sachet usage over time and between products

The major trend observed in weekly sachet usage included a sharp drop in in the second exposure month after households switched products, similar adherence between products, and minor fluctuations between the four visits in each crossover period (Figure 5.1).

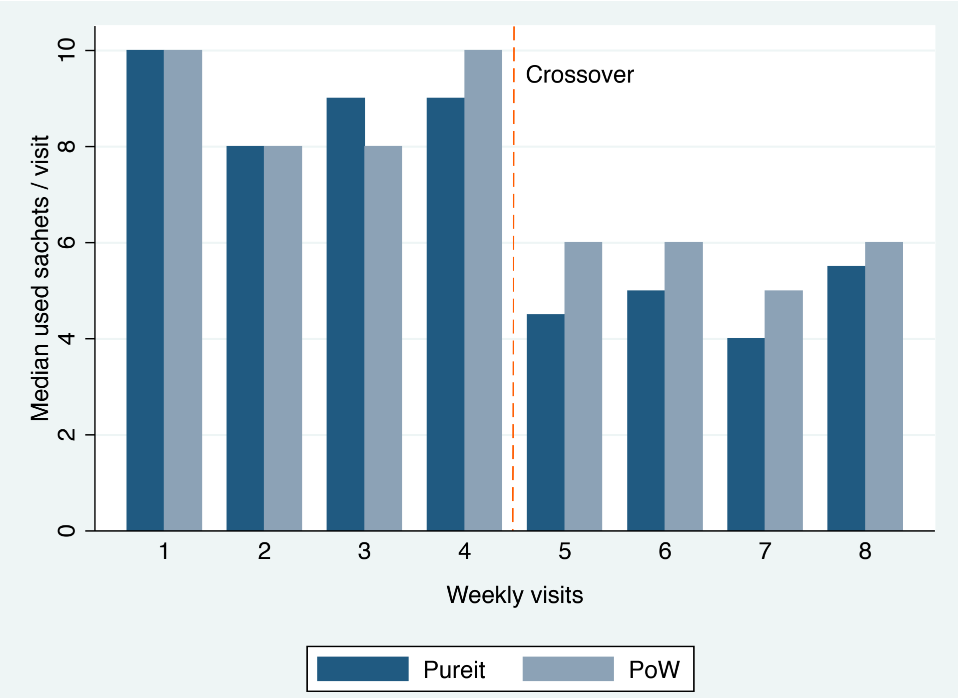
Weekly household usage dropped from a median of 9 to over 5 sachets per week over crossover period (Table 5.2). Sachet usage was similar between the two products (e.g median overall weekly sachet usage for both products: 7 sachets; median total used sachets: 30 sachets, PoW and 33 sachets, Pureit) (Appendix G, Table G1). Noteworthy differences were also observed between households. Table 5.2 illustrates households on both high and low ends of average sachet usage, though the majority (88%) used between 5-12 sachets per week.

Table 5 2 Distribution of major outcomes – Pakistan

OUTCOMES		CROSSOVER PERIOD 1	CROSSOVER PERIOD 2	ALL STUDY VISITS
Used sachets (N = 233)				
Weekly sachet usage	Median (range)	9 (0-50)	5 (0-50)	7 (0-50)
Weekly sachets used / HH				
Categories	0-4	2.4	32	6.3
(%)	4.1-8	32	37	49
	8.1-12	45	26	38
	12.1 <	20	5.6	6.8
Total (HH Visits)		848	864	1640
Total (HH)		212	216	205
Per capita daily consumption within SPHERE guideline (2.5L)				
very inconsistent	<50%	20%	46%	33%
somewhat inconsistent	50-90%	25%	20%	23%
consistent	>90%	55%	34%	45%
HH visits	n	884	866	1750
median (range)		100 (0- >100*)	57 (0- >100)	80 (0- >100)
Presence of water samples during visits N *=232				
	none	-	-	2.6***
	half or less	-	-	33
	more than half	-	-	46
	all visits	-	-	19
	Total			100
Reportedly treated samples/visit				
Samples present during visit (%)		77%	52%	65
Total HH visits (N=232)		899	890	1789
Detectable total (TC) and free (FC) chlorine in samples (N =226)				
Total samples collected (#)		696	464	1160
TC in reportedly treated samples (%)		90%	93%	91%
Detectable TC over all HH visits (%)		70%	49%	59%
FC in reportedly treated samples (%)		83%	78%	81%
Detectable FC over all HH visits (%)		64%	41%	52%
Reported untreated water consumption				
	Yes	26%	36%	31%
Total (HH)=232	Total household visits	899	890	1789

* *HH visit= household visit (up to 8 per household). HH = household*

Figure 5 1Median weekly sachet counts over 8 study visits, divided by allocated product – Pakistan *



n= 233 households (HHs).

Crossover-specific hypothesis tests

Crossover-specific hypothesis tests (Senn, 2002) employing total used sachets per crossover period found the drop in usage in the second crossover period to be highly significant (p<0.0001). Weak evidence was found of a minor "treatment effect", i.e a difference in usage based on which product was allocated (Table 5.3). The cohort of households who first received PoW used slightly more sachets than users of Pureit in the first period, and comparatively less sachets in the second period when they were assigned to Pureit, leading to a greater difference over crossover period. However, of the two calculations conducted to test treatment effect (Table 5.3), only one was significant (p=0.034). No carry over or interaction effects were observed, indicating that the order in which products were allocated had no significant influence on usage (Table 5.3).

Table 5 3 Two-by-two hypothesis tests for crossover studies (Senn, 2002) – Pakistan (n=204* households)

TESTS		Significance (p-value)	INTERPRETATION
Assessment	Details of 2x2 tests		
Period Effects (i.e difference over crossover period)	Significant difference in Pureit-Purifier of Water use, assessed over order of exposure allocation	<0.0001	Strong period effect
	Null: (Period 1 - Period 2) = 0	<0.0001	Strong period effect
Treatment Effects (i.e product difference)	Difference in usage across crossover periods, assessed over order of exposure allocation	0.038	Possible treatment effect
	Null: (Pureit - Purifier of Water)= 0	0.094	Borderline treatment effect
Carry over effects (i.e difference based on order of exposure)	Average usage between products, assessed over order of exposure allocation	0.48	No interaction effect
	Average usage between both crossover periods, assessed over order of exposure	0.48	No carry over effect

** households with missing data (i.e visits) excluded from this analysis*

Weekly sachet counts

No difference was observed in usage based on product allocation (p=0.14) (Table 5.4). A highly significant drop was observed in average usage in the second crossover period (p<0.001), including after stratifying by product (p<0.001) (Table 5.4). Usage did not change significantly between the four visits in either period (p>0.3) (Table 5.4). Zero-inflated negative binomial regression (Table 5.5) indicated a 25% drop in average weekly usage rates in the second crossover period (for all counts above 0), and 9 times the odds of non-usage (i.e 0 used sachets in the past week, *see Methods 5.2.2*) (p<0.0001). Sachet usage did not differ based on which product was allocated (p=0.31), after controlling for the change over crossover period and numbers of days between individual households visits (Table 5.5).

Table 5 4: Univariate and stratified Somer's D hypothesis tests of differences across a) crossover period and between products and b) weekly visits, for observed weekly used sachets, per capita consumption, availability of water samples, and detectable chlorine in water samples (Pakistan)

Outcome		Period 1			Period 2			All Pureit (both periods)	Purifier of Water (both periods)	Univariate (UV) and stratified differences in outcome over crossover period and between products (Somer's D✚)	
		pureit	purifier of water	both products	pureit	purifier of water	both products				
Observed weekly used sachets	median weekly used sachets (range)	9 (0-50)	9 (0-40)	9 (0-50)	5 (0-46)	6 (0-50)	5 (0-50)	7 (0-50)	7 (0-50)	Product differences (UV) ° Stratified: Phase 1° Stratified: Phase 2°	Crossover period differences (UV)*** Stratified: Pureit *** Stratified: Purifier of Water ***
n	household visits	422	461	883	444	424	868	866	885		
Per capita consumpion	% adherence to SPHERE minimum guidelines(2.5 L/person/day): median % (range)	100% (0 - >100)	100% (0 - >100)	100% (0 - >100)	55% (0->100)	63% (0 - >100)	57% (0 - >100)	79% (0->100)	80% (0->100)	Product differences (UV) ° Phase 1° Phase 2°	Crossover period differences (UV)*** Pureit ** Purifier of Water ***
n	household visits	425	459	884	443	423	866	868	882		
Availability	% of household visits with reportedly treated samples present	80%	74%	77%	50%	53%	52%	66%	64%	Product differences (UV) ° Phase 1* Phase 2°	Crossover period differences (UV)*** Pureit* Purifier of Water ***
n	household visits	455	444	899	446	444	890	901	888		
Detectable total chlorine in samples (%)	% of reportedly treated samples with detectable total chlorine	90%	90%	90%	93%	93%	93%	91%	91%	Product differences (UV) ° Phase 1° Phase 2°	Crossover period differences (UV) ** Pureit ° Purifier of Water °
n	households visits	366	329	695	225	239	464	591	568		

B)

Outcome		Weekly visits 1	2	3	4	5	6	7	8	Differences in outcome over all visits and within each crossover period (Somer's D✚) Univariate	Stratified differences
Observed weekly used sachets	median weekly used sachets (range)	10 (0-50)	8 (0-40)	8.5 (0-37)	9 (0-34)	6 (0-50)	5 (0-46)	4 (0-38)	6 (0-44)	Across all visits ***	Period 1°
n	household visits	230	221	216	216	219	216	215	218		Period 2°
Per capita consumpion	% adherence to SPHERE minimum guidelines(2.5 L/person/day): median % (range)	>100 (0 - >100)	100 (0 - >100)	95 (0 - >100)	100 (0 - >100)	44 (0 - >100)	57 (0 - >100)	57 (0 - >100)	70 (0 - >100)	Across all visits ***	Period 1°
n	household visits	231	221	216	216	218	215	215	218		Period 2***
Availability	% of household visits with reportedly treated samples present	83	72	81	73	46	52	51	60	Across all visits ***	Period 1*
n	household visits	231	225	221	222	223	223	222	222		Period 2***
Detectable total chlorine in samples (%)	% of reportedly treated samples with detectable total chlorine	94	90	87	88	93	93	92	94	Across all visits °	Period 1**
n	households visits	191	162	180	162	103	115	113	133		Period 2°

✚ *Somer's D is a non-parametric ordinal measure of association between two variables that is appropriate for clustered data. Further details can be found in Newson (2002). Exact p-values can be found in Appendix G.*

° non-significant (p≥0.1)

** borderline significance (0.1>p>0.05)*

*** significant (0.05*≥p≥0.01)

*** highly significant (p<0.01)

Table 5 5 Zero-inflated negative binomial regression examining the rate of weekly sachet usage across key parameters – Pakistan

COVARIATE	Predictor categories (% distribution) n*=233	Outcome: Rate of average weekly usage per week (non-zero values) and odds of 0 sachets used per week (for 0 values) EFFECT SIZE**		95% CI	SIGNIFICANCE (p-value***)	ADJUSTED FOR
Crossover period	baseline: 1 (50%)	IRR	0.85	0.8-0.9	<0.001	days-between-visits / product
	2 (50%)	OR	8.8	4.7-16		
Product	baseline: Pureit (51%)	IRR	1.04	0.99-1.1	0.31	days-between-visits / Crossover period
	Purifier of Water (49%)	OR	0.95	0.65-1.4		
Untreated water consumption	baseline: no (69%)	IRR	0.87	0.8-0.95	0.0001	Crossover period / Product / days-between-visits
	yes (31%)	OR	1.7	1.2-2.4		
Consumption of alternate product	baseline: no (82%)	IRR	0.93	0.82-1.05	<0.0001	Crossover period / Product / days-between-visits
	yes (18%)	OR	4.3	2.8-6.7		

**n=households*
*** Every outcome for a given independent variable in the zero-inflated negative binomial models is associated with two components: IRRs for all positive integers (i.e sachet counts ≥1), and odds ratios (ORs) comparing the odds of 0 sachets to ≥1 sachets (i.e. representing the odds of no sachets being used, reported as "non-usage" in this manuscript).*
**** Wald's p-values including both components of the zero-inflated model (IRR and ORR)*

5.3.1.3 Trends in water consumption

Per capita consumption:

Median adherence to the SPHERE minimum (2.5L /capita/day) dropped drastically in the second crossover period from 100% to 57% (p<0.001) (Table 5.4). Over 55% of households were in the most adherent category (>90%) in the first crossover period, dropping to under 34% in the second. Median household usage was 2.5L in the first crossover period, dropping to 1.43L in the second. Over 58% of households consumed less than 2.5 L per capita over all visits, and over 11 % consumed more than 5 L per capita (Appendix G Table G3). Generalized ordered logistic regression modelled the odds of SPHERE adherence levels being in categories >50% and >90%, respectively. Table 5.6 indicates a roughly 30 - 40% drop in the odds of both higher adherence categories in the second crossover period (OR >50%=0.32, p<0.001; OR >90%=0.44, p<0.001). There was a borderline significant difference in adherence levels between products (p=0.088) (Table 5.6).

Water samples

Over 18% of households had samples of reportedly treated water over all visits, 46% had samples present during more than half (though not all), and less than 3% never had samples present (Table 5.2). On average, approximately 60% of all study households had treated water with detectable chlorine in the first crossover period, and over 48% did so in the second period (Table 5.2). The odds of observing detectable chlorine in water samples rose by more than one and a half times in the second crossover period (p=0.03), though equal for both products (p=0.35) (Table 5.7).

Concurrent untreated water consumption

Nearly 31% of households reported consuming untreated water alongside treated water, rising from approximately 25 - 36% over crossover periods (including 17% in both crossover periods where untreated water was consumed as much or more than treated water) (Table 5.2). The relationship between untreated water was assessed across our different outcome measures:

- Reportedly consuming untreated water (as a binary option) was strongly associated with average weekly usage (p<0.0001), leading to over 10% reductions in average positive (non-zero) counts, and nearly twice the odds of no usage (Table 5.5).
- Untreated water consumption also reduced the odds of a household being in SPHERE-minimum adherence categories above 50% to OR 0.72 (p=0.004), and of being above 90% to OR 0.63 (p<0.001) (Table 5.8). No association was found between the odds of detectable chlorine and reported consumption of untreated water (p=0.32, Table 5.7).
- Consuming untreated water was associated with lower odds of using one or more sachet/day/visit for both stated (p<0.001) (Table 5.9) and observed (p=0.009) sachet outcomes (Appendix G Table G 5), measures that are discussed further in section 5.3.1.4.

Table 5 6 Generalized ordered logistic regression examining user-estimated per capita consumption over key parameters – Pakistan

COVARIATE	Predictor categories (% distribution) n*=233	Outcome: Odds of >50% and >90% adherence to SPHERE consumption guidelines				
		EFFECT SIZE**		95% CI	SIGNIFICANCE (p-value)***	ADJUSTED FOR
Crossover period	baseline: 1 (50%)	OR > 50% adherence	0.33	0.26-0.41	<0.0001***	days-between-visits
	2 (50%)	OR > 90% adherence	0.44	0.36-0.52		
Product	baseline: Pureit (50%)	OR > 50% adherence	1.3	1.02-1.5	0.088***	
	Purifier of Water (50%)	OR > 90% adherence	1.07	0.9-1.3		
Untreated water consumption	baseline: no (69%)	OR > 50% adherence	0.72	0.57-0.9	0.0011	Crossover period / Product / days-between-visits
	yes (31%)	OR > 90% adherence	0.63	0.49-0.81		

**n=households*

*** Generalized ordered logistic regression for a predictor variable with 3 categories A,B,C presents two coefficients: the odds of being in category B or C vs A, and the odds of being in category C vs A&B. This is represented in the two rows (OR>50% and OR >90% next to each predictor.*

**** Wald's p-values including both components of the ordered logistic model (OR of >50% and >90%)*

Table 5 7 Logistic regression examining the odds samples having detectable total chlorine across key parameters – Pakistan

COVARIATE	Predictor categories (% distribution) n*=225	Outcome: Odds of detectable total chlorine ≥ 0.2 vs <0.2 mg/l (baseline)			
		EFFECT SIZE (OR)	95% CI	P-VALUE	CONTROLLING FOR
Crossover period	1 (50%)	1			
	2 (50%)	1.6	1.05-2.6	0.029	Product / days-between-visits
Product	Pureit (51%)	1			
	Purifier of Water (49%)	0.99	0.66-1.5	0.94	Crossover period / days-between-visits
Untreated water consumption	no (69%)	1			
	yes (31%)	1.3	0.79-2.1	0.3	Crossover period / Product / days-between-visits
Observed daily usage	<1 packet/day (44%)	1			
	≥1 packet/day (56%)	1.01	0.66-1.5	0.96	Crossover period / Product / days-between-visits
Stated daily usage	<1 packet/day (6%)	1			
	≥1 packet/day (94%)	1.07	0.27-4.3	0.92	Crossover period / Product / days-between-visits

**n=households*

5.3.1.4 Observed sachet usage over time and between products:

Self-reported usage was noticeably greater than observed usage, as illustrated in Figure 5.2. Between 80-90% of observed estimates were in higher categories of stated usage (Appendix G Table G7). Less than 0.4% of stated usage responses reported zero-usage in the previous week, in contrast to 13% of observed findings. Logistic regression indicated that the odds of stated sachet usage were nearly 5 times more likely to be ≥ 1 sachet/day as compared to observed sachets ($p<0.001$), after controlling for product, crossover period, and days-between-visits (Table 5.8). The odds of detectable chlorine were also assessed across observed and stated usage categories, to further explore any differences between the two. The odds of detectable chlorine were not significantly higher across categories of either observed or stated usage (Table 5.7).

Figure 5 2 Frequencies of observed and stated daily rates of sachet usage per visit – Pakistan (n=233 HH)

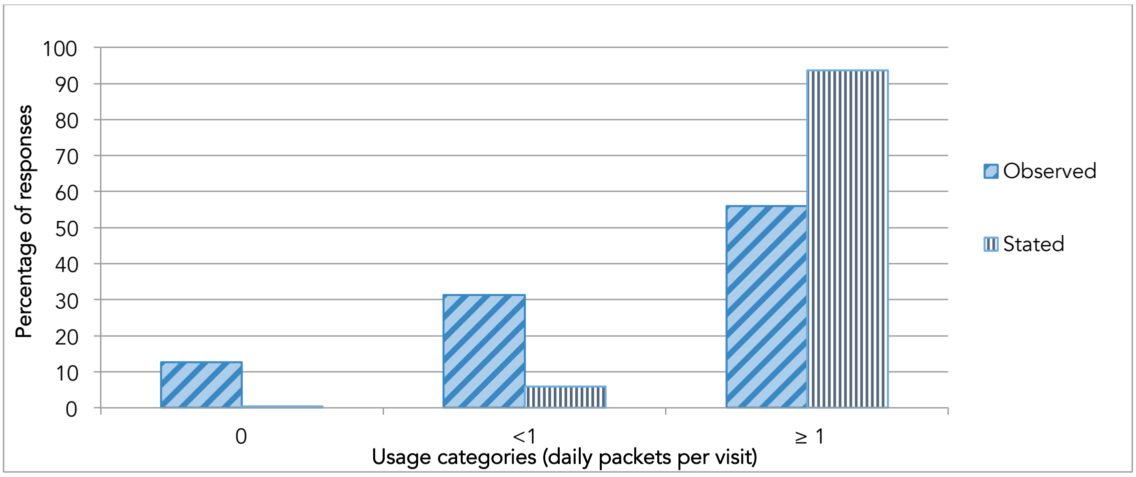


Table 5 8 Logistic regression examining the odds of stated packet usage across categories of observed usage and untreated water consumption status Pakistan

COVARIATE	Predictor categories (% distribution) n*=232	Outcome : Odds of stated use ≥1 packet /day vs <1packet/day EFFECT SIZE (OR)	95% CI	P-VALUE	ADJUSTED FOR
Observed packet categories	<1 packet/day (44%)	1			
	≥1 packet/day (56%)	4.8	2.8-8.4	<0.001	Crossover period / Product / days-between-visits
Untreated water consumption	no (69%)	1			
	yes (31%)	0.16	0.09-0.25	<0.001	Crossover period / Product / days-between-visits

**n=households*

5.3.2 ZAMBIA CASE STUDY

5.3.2.1 Descriptive findings

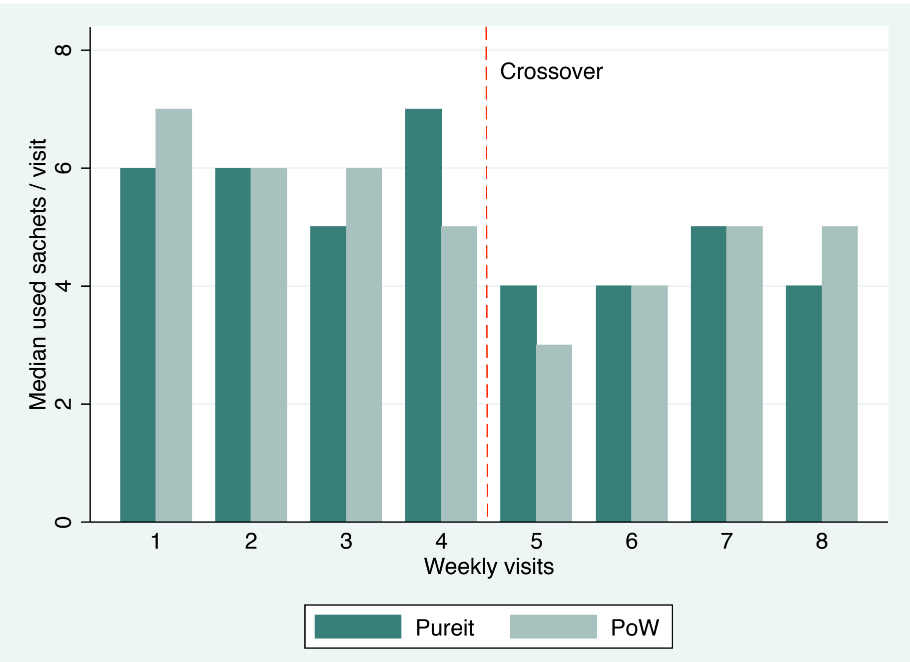
See Section 4.3.2.1 (Chapter 4) and Appendix D (Table D2) for an outline of descriptive findings that will be used in published versions of this chapter.

5.3.2.2 Trends in used sachets over time and between products

Usage overview

A sharp reduction in weekly used sachets was observed in the second crossover period, and no discernible difference was found between the two products, illustrated in Figure 5.3. Median usage per visit dropped from 6 sachets in the first crossover period to 4 sachets in the second period (Table 5.9). Median total Pureit sachets used were nearly the same as those for PoW use (23 and 22 sachets/month, respectively), and weekly usage per period was identical (Appendix G, Table G2). Over the entire study, 16% of households used 0 - 4 sachets/week on average, and the majority (over 57%) used between 5 - 8 sachets/week (Table 5.9).

Figure 5 3 Median used sachets per visit for Pureit and PoW – Zambia *



** n=204 HHs*

Table 5 9: Distribution of major outcomes – Zambia

OUTCOMES		CROSSOVER PERIOD 1	CROSSOVER PERIOD 2	ALL STUDY VISITS
Used sachets (n=204)				
Weekly sachet usage	Median (range)	6 (0-64)	4 (0-48)	5 (0-64)
Weekly sachets used / HH				
Categories (%)	0-4	16	39	17
	4.1-8	40	44	57
	8.1-12	32	12	21
	12.1 <	12	4.6	4.9
Total (HH)		189	196	185
Per capita daily consumption within SPHERE guideline (2.5L)				
very inconsistent	<50%	42%	55%	49%
somewhat inconsistent	50-90%	26%	23%	25%
consistent	>90%	31%	22%	27%
HH visits	n	791	779	1570
median (range)		57 (0 - >100*)	44 (0 - >100)	50 (0 - >100)
Reported untreated water consumption				
	Yes	49%	62%	55%
Total (HH)=204	Total household visits	808	775	1583
Presence of water samples during visits				
	none	-	-	3.2
	half or less	-	-	49
	more than half	-	-	43
	all visits	-	-	4.3
n=185	Total			100
Reportedly treated samples/visit				
Samples present during visit (%)		54%	47%	50%
Total HH visits (n=204)		780	734	1514
Detectable total (TC) and free (FC) chlorine in samples (n =226)				
Total samples collected (#)		419	364	764
TC in reportedly treated samples (%)		56%	63%	59%
Detectable TC over all HH visits (%)		30%	30%	30%
FC in reportedly treated samples (%)		42%	52%	46%
Detectable FC over all HH visits (%)		22%	24%	23%

** >100 : percentages were greater than 100% as the calculation was the compliance to SPHERE minimum guidelines - 2.5L/person/day (i.e if 5 L/person/day was consumed, it was 200%)*

Crossover specific analysis

Employing total used sachets at the end of each crossover period to assess crossover effects (Senn 2002) indicated a highly significant drop over study period ($p<0.001$), and no significant difference based on product exposure ($p>0.5$), or the order in which products were allocated ($p=0.19$) (Table 5.10).

Table 5 10: Two-by-two hypothesis tests for crossover studies (Senn, 2002) – Zambia (n=185* households)

TESTS: Assessment	TESTS: Details of 2x2 test	Significance (p-value)	INTERPRETATION
Period Effects (i.e difference over crossover period)	Significant difference in Pureit-PoW use, assessed over order of exposure allocation	<0.0001	Strong period effect
	Null: (Period 1 - Period 2) = 0	<0.0001	Strong period effect
Treatment Effects (i.e product difference)	Difference in usage across crossover periods, assessed over order of exposure allocation	0.79	No treatment effect
	Null: (Pureit – PoW) = 0	0.59	No treatment effect
Carry over effects (i.e difference based on order of exposure)	Average usage between products, assessed over order of exposure allocation	0.19	No interaction effect
	Average usage between both crossover periods, assessed over order of exposure	0.19	No carry over effect

** households with missing data (i.e visits) excluded from this analysis*

Weekly sachet counts

A highly significant drop was observed in usage in the second crossover period ($p<0.001$), and no significant difference based on product allocation ($p=0.67$) (Table 5.11). Weekly usage varied significantly across the four visits of the second crossover period ($p>0.001$), though not in the first period. Negative binomial regression (Table 5.12) indicated a 30% lower rate of weekly usage in the second crossover period ($p>0.001$), after controlling for product allocation and days between household visits. No significant difference was observed in usage rates based on product allocation ($p=0.64$).

Table 5 11: Univariate and stratified Somer's D hypothesis tests of differences across a) crossover period and between products and b) weekly visits, for observed weekly used sachets, per capita consumption, availability of water samples, and detectable chlorine in water samples (Zambia)

Outcome		period 1 pureit	period 1 purifier of water	period 1 both products	period 2 pureit	period 2 purifier of water	period 2 both products	All Pureit (both periods)	Purifier of Water (both periods)	Univariate (UV) and stratified differences in outcome over crossover period and between products (Somer's D+)	
Observed weekly used sachets	median weekly used sachets (range)	6 (0-62)	6 (0-64)	6 (0-64)	4 (0-48)	4 (0-28)	4 (0-48)	5 (0-62)	5 (0-64)	Product differences (UV)°	Crossover period differences (UV)***
n	household visits	404	387	791	372	412	784	776	799	Stratified: Phase 1° Stratified: Phase 2°	Stratified: Pureit *** Stratified: Purifier of Water ***
Per capita consumpion	% adherence to SPHERE minimum guidelines(2.5 L/person/day): median % (range)	57 (0 - >100)	62 (0 - >100)	57 (0- >100)	46 (0 - >100)	41 (0 - >100)	44 (0- >100)	52 (0 - >100)	50 (0 - >100)	Product differences (UV)°	Crossover period differences (UV)***
n	household visits	404	387	791	370	409	779	774	796	Phase 1° Phase 2°	Pureit ** Purifier of Water ***
Availability	% of household visits with reportedly treated samples present	49	59	54	50	44	47	49	51	Product differences (UV)°	Crossover period differences (UV)***
n	household visits	403	377	780	347	387	734	750	764	Phase 1** Phase 2°	Pureit ° Purifier of Water ***
Detectable total chlorine in samples (%)	% of reportedly treated samples with detectable total chlorine	63	49	56	66	60	63	64	54	Product differences (UV)***	Crossover period differences (UV)*
n	households visits	197	222	419	174	171	345	371	393	Phase 1*** Phase 2°	Pureit ° Purifier of Water *

B)

Outcome		Weekly visits								Differences in outcome over all visits and within each crossover period (Somer's D✚)	
		1	2	3	4	5	6	7	8	Univariate	Stratified differences
Observed weekly used sachets	median weekly used sachets (range)	6 (0-47)	6 (0-52)	5 (0-64)	6 (0-51)	3 (0-23)	4 (0-26)	5 (0-48)	4 (0-28)	Across all visits ***	Period 1°
n	household visits	204	200	197	190	197	196	195	196		Period 2***
Per capita consumpion	% adherence to SPHERE minimum guidelines(2.5 L/person/day): median % (range)	52 (0->100)	57 (0->100)	57 (0->100)	70 (0->100)	40 (0->100)	46 (0->100)	44 (0->100)	44 (0->100)	Across all visits ***	Period 1 **
n	household visits	204	200	197	190	196	193	195	195		Period 2°
Availability	% of household visits with reportedly treated samples present	62	59	51	43	67	42	39	38	Across all visits ***	Period 1***
n	household visits	195	201	200	184	193	177	176	188		Period 2***
Detectable total chlorine in samples (%)	% of reportedly treated samples with detectable total chlorine	50	59	57	57	67	67	66	50	Across all visits °	Period 1°
n	households visits	120	119	101	79	130	75	68	72		Period 2**

✚ *Somer's D is a non-parametric ordinal measure of association between two variables that is appropriate for clustered data. Further details can be found in Newson (2002). Exact p-values can be found in Appendix G.*

° non-significant ($p \geq 0.1$)

** borderline significance ($0.1 > p > 0.05$)*

*** significant ($0.05 \geq p \geq 0.01$)*

*** highly significant ($p < 0.01$)

Table 5 12 Negative binomial regression examining the rate of weekly sachet usage across key parameters– Zambia

COVARIATE	Predictor categories (% distribution) n*=204	Outcome: Rate of average usage per week EFFECT SIZE (IRR**)	95% CI	P-VALUE	ADJUSTED FOR
Crossover period	1 (50%)	1			
	2 (50%)	0.7	0.64-0.77	<0.001	product / days-between-visits
Product	Pureit (50%)	1			
	Purifier of Water (50%)	1.02	0.93-1.1	0.64	Crossover period / days-between-visits
Untreated water consumption	no (45%)	1			
	yes (55%)	0.93	0.84-1.04	0.2	Crossover period / product / days-between-visits
Shared packets with other households	no (94%)	1			
	yes (6%)	0.83	0.62-1.1	0.2	Crossover period / product / days-between-visits

**n=households*
*** incidence rate ratio*

5.3.2.3 Trends in water consumption

Per capita consumption

Overall adherence to SPHERE minimum consumption guidelines was 50% (median value), dropping from over 57% to 44% over the two crossover periods (Table 5.9). The majority (over 49%) of households fell in the lowest category of SPHERE guideline adherence (<50%), and over a quarter were in the highest (>90%) (Table 5.9). Over 75% of households consumed less than 2.5L/capita/day overall, over 17% consumed between 2.5-5L, and approximately 7% consumed more than 5 L (the 99th percentile reached over 12L) (Appendix G Table G4). Ordered logistic regression indicated over 40% lower odds of being in a higher category of adherence in the second crossover period (p<0.001, Table 5.15), and no difference between products (p=0.76) (Table 5.13).

Water Samples

Households had drinking-water (treated or not) on the premises during more than 94% of household visits[2]. However, drinking-water was only *reportedly* treated in 50% of all visits, decreasing slightly over crossover period from over 53% to 47% (Table 5.9). Furthermore, detectable total chlorine was only observed in approximately 59% of reportedly treated samples, increasing over crossover period from over 55 - 63% (p=0.049) (Table 5.9, Table 5.11). In total, under 30% of all study households had detectable total chlorine in their water samples at any one time (similar across crossover periods). Less than 5% of households had treated water samples available at all visits, and the majority (over 52%) had samples present during half or less of all visits (Table 5.9).

The odds of detectable chlorine in water samples were approximately 35% lower in PoW samples, relative to Pureit (p=0.006), and slightly higher in the second crossover period, though this was only of borderline significance (OR 1.32 p=0.088) (Tale 5.14).

Untreated water consumption

Households also reported consuming untreated water alongside treated water throughout the study, rising from approximately 49% in the first crossover period, and increasing to 62% in the second (Table 5.9). Approximately 5% of households also reported sharing their sachets with other households that were not part of the study (typically neighbours or family members). The relationship between untreated water was assessed across our different outcome measures:

- No significant relationship was found between weekly usage and self reported consumption of untreated water (p=0.2) (Table 5.12).
- A 20% decrease in the odds of higher adherence to SPHERE minimum guidelines was observed in households who reported consuming untreated water (p=0.044) (Table 5.13).
- The odds of observed sachet counts ≥ 1 sachet/day decreased when households reported consuming untreated water (OR 0.76 p=0.019) (Appendix G, Table G4), whereas stated daily use indicated considerably *higher* odds of stated usage if households reported consuming untreated water (OR 1.9 p<0.001) (Table 5.15). The comparison between these measures is further discussed in section 5.3.2.4.

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[2] *The Zambia dataset included the presence or absence of any water upon the premises, while this information was missing in Pakistan due to an error in data collection.*

Table 5 13 Ordered logistic regression examining the odds of greater per capita consumption across key parameters – Zambia

COVARIATE	Predictor categories (% distribution) n*=204	Outcome**: Odds of higher categories of adherence to SPHERE minimum (i.e ≥50% vs < 50% & ≥90% vs <90%) EFFECT SIZE (OR)	95% CI	P-VALUE	ADJUSTED FOR
Crossover period	1 (50%)	1			
	2 (50%)	0.59	0.49-0.7	<0.001	product / days-between-visits
Product	Pureit (50%)	1			
	Purifier of Water (50%)	0.97	0.81-1.16	0.76	crossover period / days-between-visits
Untreated water consumption	no (45%)	1			
	yes (55%)	0.8	0.65-0.99	0.044	crossover period / product / days-between-visits

**n=households*

*** ordered logistic regression, observing the assumptions of proportional odds presents the odds of being in higher categories of the dependent variable. Ordered logistic regression with 3 categories A,B,C presents one outcome representing the odds of the outcome being in category B or C vs A, and the odds of being in category C vs A&B.*

Table 5 14 Logistic regression examining the odds of water samples having detectable total chlorine across key parameters – Zambia

COVARIATE	Predictor categories (% distribution) n*=194	Odds of detectable total chlorine ≥ 0.2 vs <0.2 mg/l (baseline) EFFECT SIZE (OR**)	95% CI	P-VALUE	ADJUSTED FOR
Crossover period	1 (50%)	1			
	2 (50%)	1.3	0.96-1.8	0.088	Product / days-between-visit
Product	Pureit (50%)	1			
	Purifier of Water (50%)	0.64	0.47-0.88	0.006	Crossover period / days-between-visit
Untreated water consumption	no (45%)	1			
	yes (55%)	0.76	0.58-0.99	0.04	Crossover period / Product / days-between-visit
Observed daily usage	<1 packet/day (61%)	1			
	≥1 packet/day (39%)	1.6	1.2-2.2	0.002	Crossover period / Product / days-between-visit
Stated daily usage	<1 packet/day (25%)	1			
	≥1 packet/day (75%)	0.88	0.61-1.3	0.51	Crossover period / Product / days-between-visit

**n=households*

*** odds ratio*

5.3.2.4 Observed vs Stated sachet usage

Households self-reported non-usage (0 sachets used since the previous visit) on 0.3% of visits, though non-usage was recorded in 7% of observed sachet counts. Over 74% of observed usage rates below 1 sachet/day were in higher stated categories (Appendix G Table G8). However, over 23% of observed sachets ≥ 1 sachet/day were also stated as being <1 sachet/day, supporting the observed lack of significant correlation. Logistic regression indicated that the odds of stated sachet counts ≥ 1 sachet/day were not significantly associated with observed sachet counts (OR 1.14, p=0.39), suggesting little correlation between the two outcomes (Table 5.15). The odds of detectable chlorine were also assessed across observed and stated usage categories, to further explore any differences between the two. Greater odds of detectable chlorine were noted in households whose observed daily use was ≥ 1 sachet/day (OR 1.63, p=0.003), whereas no significant association was found when the same analysis was conducted with stated daily rates (OR 0.88, p=0.51) (Table 5.14).

Figure 5 4: Frequencies of observed and stated daily rates of sachet usage per visit - Zambia (n=204)

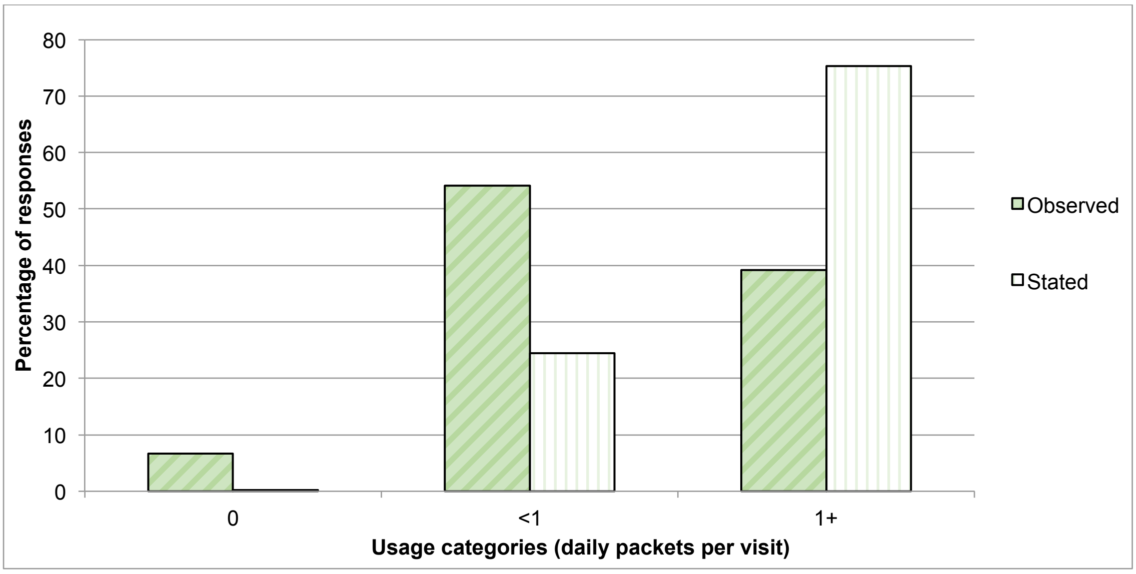

Table 5 15 Logistic regression examining the odds of stated packet usage across categories of observed usage and untreated water consumption status – Zambia

COVARIATE	Predictor categories (% distribution) n*=204	Outcome: Odds of stated use ≥1 vs <1packet/day (baseline) EFFECT SIZE (OR**)	95% CI	P-VALUE	Adjusted for
Observed daily usage	<1 packet/day (61%)	1			
	≥1 packet/day (39%)	1.1	0.86-1.5	0.39	crossover period / product / days-since-visit
Untreated water consumption	no (45%)	1			
	yes (55%)	1.9	1.5-2.6	<0.001	crossover period / product / days-since-visit

**n=households*
*** odds ratio*

5.4 DISCUSSION

5.4.1 Key findings

Our two-country, multiple measure crossover assessment of adherence indicated a sharp decrease in observed product usage over time, generally low and decreasing consumption of treated water, and notable differences between self-reported and observed measures.

Product adherence

Lower adherence, together with an increase in concurrent untreated water consumption was observed in both countries over a short period of time, most notably over the crossover period. This trend was apparent across measures of observed weekly usage, per capita consumption of treated water, overall adherence per crossover period, and availability of treated water samples. The health impact afforded by POU is determined by the consumption of safe water(Brown and Clasen, 2012; Cairncross and Valdmanis, 2006), as observed in water samples and estimations of litres of treated water per capita, and as opposed to mere access to safe water. The highest per capita consumption observed in this study was in the first crossover period in Pakistan where it was exactly 2.5L, and decreased in the second period by over 40%. Furthermore, 2.5L is a conservative estimate for the minimum quantity of safe water required in emergencies, contrasting with the WHO recommended 7.5L per capita to provide for basic hydration and incorporation into food(WHO, 2011). Moreover, WHO estimate 15L during emergencies, and 20L to cover basic hygiene needs and food hygiene (Reed et al., 2013). Concurrent untreated water consumption further reduces POU adherence estimates, as it is the total proportion of water consumption that is safe which determines health impact (Brown and Clasen, 2012; Enger et al., 2013; Hunter et al., 2009).

Our findings of variable and overall low POU adherence are consistent with several POU studies (Albert et al., 2010; Luoto et al., 2011), including observing reductions in adherence over time (Hunter, 2009), and the concomitant consumption of untreated water(Boisson et al., 2010; Rosa et al., 2014). These are factors that could greatly mitigate any protective effects from treated water (Brown and Clasen, 2012; Enger et al., 2013; Hunter et al., 2009) and suggest that adherence in this study would not have yielded substantial protective health effects. This questions the notion that short term, high-follow-up contexts may be one of the most appropriate for POU(Schmidt and Cairncross, 2009), and supports many of the few available studies of uptake in emergency contexts (Colindres et al., 2007; Doocy and Burnham, 2006; Lantagne and Clasen, 2012). Our findings also support recent POU monitoring guidance published by the WHO suggesting using a combination of water quality measures and objective usage indicators, as well as taking longitudinal measurements (WHO, 2012). It is noteworthy that this study examined adherence to products that were distributed for free. Implementing the intervention at user cost may well have resulted in different levels and patterns of adherence. For example, the total proportion of households engaging in the behaviour at all may have been lower, though consistency of usage amongst users may have been higher.

Observed and self-reported use

Both country studies revealed clear and sizable differences between observed and stated sachet usage, and greater stated usage overall (Figures 5.2 and 5.3). It is surmised that the inflation of stated values was a combination of recall bias (inflated towards greater use) in self-reported estimates, and to an extent, conscious exaggeration (most notably in Zambia). Over 80% of observed sachet counts were in higher categories of stated usage in Pakistan, with five times the odds of higher stated usage observed from regression modelling. In Zambia, between 65-75% of observed values were in higher categories of stated usage. Regression estimates from the Zambia study did not reveal any significant association between the two, and chi-squared tests indicated no significant correlation. This could suggest that the relationship between the two outcomes was even weaker than in Pakistan, and/or that observed estimates in Zambia were subject to similar biases as stated outcomes. In addition, whereas lower observed sachet usage was correlated to untreated water consumption, stated usage in Zambia appeared to actually increase among households who reported consuming untreated water, further supporting the greater bias in these measures in Zambia. In Pakistan, both observed and stated outcomes decreased with untreated water consumption, and neither differed in households with detectable chlorine during visits as the proportion of chlorine was so high overall.

Several other studies have also found significant bias in self-reported usage data(Arnold et al., 2009; Brown and Sobsey, 2012; Colindres et al., 2007; Rosa, 2012). Rosa found lower observed treatment and concurrent usage of untreated water in all three of her country studies (interestingly, the greatest difference was in Zambia), concluding that self-reported usage was a weak indicator of adherence (Rosa, 2012). Arnold et al (2009) found at self-reported use was 3.8 - 6.4 times higher than observed in a solar-disinfection intervention in Guatemala (Arnold et al., 2009), similar to our regression estimates in Pakistan. It is noteworthy that intention-to-treat (ITT) analysis would have employed a measure that was even more biased towards higher adherence than self-reported usage. In this study, ITT could have assumed 100% adherence to SPHERE minimum guidelines for treated water (Sphere Project, 2011) for example, which would include assuming equal adherence by the entire study population, and constant adherence over time – which our observed findings proved to be far from the case.

5.4.2 Country and product differences

Usage was greater and more consistent in Pakistan than in Zambia across all outcome measures. Though the proportion of water samples in Pakistan dropped by over 30% in the second crossover period, this was in line with the median decrease in used sachets, and the vast majority (over 90%) of reported samples had detectable total chlorine, indicating the accuracy of reported treatment. In Zambia however, only 60% of reportedly treated samples had detectable chlorine, available water samples decreased over crossover period by a smaller amount than sachet usage (only ≈ 6%), and more detectable chlorine was observed in the second crossover period. Furthermore, regression estimates of the odds of detectable chlorine did not differ in Pakistan across crossover period, product, or daily usage categories, due to the high proportion of chlorine in all samples. In contrast, greater daily usage was predictive of more detectable chlorine in Zambia, suggesting that households in lower categories of usage were less likely to have detectable chlorine in reportedly treated samples.

Our findings have noteworthy parallels in previous studies assessing the success of POU in Zambia - one of the few countries to have implemented a national-level POU programme. Rosa's multi-country assessment of POU usage in communities in Peru, India and Zambia found the lowest overall adherence to be in Zambia (Rosa, 2012). Her evaluation was conducted in a community that was closely situated to our own. Olembo and colleagues (2004) reviewed the national level Safe Water System programme in several districts, finding that only 42% of households that were exposed to the programme reported current use, and of them, only a further one third were found to have treated water at home (Olembo et al., 2004).

Sachet usage did not differ greatly based on which product was allocated. Weak evidence was found for a slightly greater difference in usage between crossover periods among households who were first allocated PoW in Pakistan. However, this was only observed in the crossover-specific calculations with total sachets and analysis of consumption according to SPHERE guidelines. This may indicate a slight preference for PoW. As discussed in other publications (Chapter 4, Chapter 6), households in both study sites reported a slight preference for PoW over Pureit, though households often gave similar reasons for supporting either, giving the impression that product differences were negligible to usage. These findings also indicate how the choice of adherence measures and analytical methods can affect a study's conclusions, further underlining the importance of thorough measurements.

5.4.3 Comparison of measures employed

Detectable total chlorine levels in water samples provided an estimate of how much treated water was present on average, and was an indicator of the accuracy of self-reported treatment. However, water samples were not a sufficient replacement for observed sachet usage as they could not represent usage at any point beyond the visit in question, and their levels were contingent on when households treated water and whether any water remained at the time of the visit. Observed sachet usage provided a valuable measure to assess usage since the past visit, trends over time, and to calculate daily usage rates and per capita consumption. Combining these two measures was found to be the most accurate manner to assess adherence.

Observed sachets were measured in several different ways. Used sachets per visit were the most accurate measure, capturing the variability across individual visits and within households. Total sachets were only used for a minor part of this analysis as they failed to capture any variation within each period of exposure. Daily usage was calculated based on the assumption that weekly usage was evenly distributed across households. This was useful to estimate how much safe water was being consumed on a daily level, but was less accurate than the objective sachet counts given the assumption that usage was identical every day since the previous visit. It also provided figures that were often fractions, and less intuitive to interpret or differentiate from one another, and challenging to use in models that were designed for count data (e.g it was impossible to use in negative binomial or zero-inflated models).

5.4.4 Limitations

This study aimed to assess usage in settings that were representative of short-term uptake in emergency-prone areas, in as much of a "real-world" manner as possible. However several areas may have introduced courtesy bias including being: overtly a trial, conducted during a non-emergency period, conducted in areas familiar with Oxfam GB and partner agencies, and most importantly, frequently visited in repeat follow-ups. Households were provided with all the necessary supplemental material to treat their water, which could have acted as further incentive to join the study. Given the high degree of follow-up and support, these findings could be considered to be a best-case scenario of usage. Less frequent visits or intrusive methods of measuring sachet usage may have yielded more objective findings. Due to an error in data collection, the Pakistan country study did not include the presence of any water (treated or not) during repeat visits, in contrast with Zambia.

5.4.5 Conclusions

This study adds to the evidence base on POU usage with a rigorous study design, repeated observations, a range of measures, and the ability to compare usage in two different settings. Adherence to either of the two products assessed was not likely to yield protective effects in this assessment. Our findings underline the importance of accurately and objectively assessing POU adherence, and the need to include careful adherence measures in future POU studies , and suggest interpreting findings using self-reported and other non-objective indicators with caution.

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Chapter 6. Exploring correlates of short-term adherence for two point-of-use water treatment products in Pakistan and Zambia: a mixed-methods longitudinal crossover study

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Principal Supervisor	Sandy Cairncross
Thesis Title	A field performance and adherence study of point-of-use water treatment in Zambia and Pakistan

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ABSTRACT

Evaluating drivers and barriers behind adherence to point-of-use (POU) water treatment may be critical to help interventions ensure the consistency of use needed to achieve health impact. This study investigates correlates of adherence in a mixed methods longitudinal crossover trial comparing two flocculant-disinfectant products in peri-urban Sindh, Pakistan and urban Lusaka, Zambia: the Pureit® sachet and the Purifier of Water®. A weekly survey was administered to over 200 households in emergency-prone settings, including adherence data and a range of potential predictors of usage. Implementation was representative of short-term usage settings, and did not include a behavioural component. Semi-structured interviews and focus group discussions were collected from a subsample of households on product feedback and drivers and barriers to adherence. Triangulating descriptive survey responses, exploratory regression analyses, and qualitative findings suggested a complex interplay between drivers and barriers.

The major trends in observed adherence included: a drop in average weekly sachet usage and a rise in untreated water over time, as well as relatively greater adherence in Pakistan. To a lesser extent, greater adherence was observed in certain subgroups within each study site. Our interpretation was that major factors determining adherence were community-level norms and perceptions surrounding the need to treat water regularly, the quality of the primary water source, and product-related costs outweighing the benefits. The perceived need to treat water was ultimately purposive, based on circumstantial factors that influenced quality perceptions. The strongest product-related drivers appeared to be immediate and apparent factors such as turbidity removal. Major barriers included the effort of treating water, and a lack of familiarity with the products. Knowledge of product usage, and health risks associated to water was high in both countries, and unrelated to adherence. Previous water-treatment habits and experiences, lower consumption of untreated water, greater use of the products for non-drinking purposes were associated to greater adherence in subgroups of each countries population.

Greater implementation efforts may have been required for adequate short-term adherence to the products investigated in our study setting. Our findings also underline the challenges to POU adherence, suggesting further research in understanding behavioural factors, and in POU design, focussing on reducing the effort required for adherence and improving immediate benefits of usage.

6.1 INTRODUCTION

It is estimated that 663 million people lack access to an improved water source(WHO/UNICEF, 2015), and that as many as 1.8 billion people may consume water at risk of faecal contamination(Bain et al., 2014). Point-of-use (POU) water treatment methods are employed by national, non-governmental and private agencies to provide access to safe water, often in short-term settings(Clasen, 2015). However, the impact, scope, and best-practises for the varied and growing number of POU methods are uncertain, and the subject of on-going research and discussion (Clasen et al., 2007; Fewtrell et al., 2005; Schmidt and Cairncross, 2009; Waddington et al., 2009). One of the key factors to optimize the health impact of POU is high adherence, which is to say, correct, consistent, and perhaps exclusive usage of a given method for its intended time of use(Brown and Clasen, 2012; Enger et al., 2013; Hunter et al., 2009). High adherence to POU usage requires considerable behaviour change, and is challenging to measure accurately. Together with better measurements of POU adherence, understanding contextual and behavioural factors interacting with and influencing adherence may be critical to improving correct and consistent use (Fiebelkorn et al., 2012). This paper investigates correlates of adherence from a multi-site longitudinal crossover assessment evaluating the uptake of two flocculant-disinfectant POU methods in urban Zambia and semi-rural Pakistan.

High POU adherence can be considerably challenging for target populations to implement, and for evaluators to assess. Although near-perfect adherence to POU treatment has been identified as critical to delivering health impacts afforded by access to safer water(Brown and Clasen, 2012; Enger et al., 2013; Hunter et al., 2009), there is little consensus on how it should be defined or measured in field studies (Clasen, 2015; Hulland et al., 2015; Waddington et al., 2009). Adherence to some POU methods may be easier to objectively measure than others: for example, disinfection by chlorination may result in detectable chlorine residual(Murray and Lantagne, 2015), but filtration or boiling may be difficult to independently verify to corroborate self-reported behaviour(WHO, 2012). POU interventions may often be less intuitive, more complicated, and different to traditional water treatment and storage practises, particularly for the most vulnerable demographic groups(Clasen, 2015). Characteristics of water treated by such methods may require considerable adaptation to render acceptable and maintain user-consistency. Flocculant-disinfectants, also known as coagulant disinfectant products (CDPs) may be particularly intensive, needing several steps including stirring, decanting and waiting, all within set volumetric and time parameters(Aquaya, 2005; Souter et al., 2003). Such behavioural requirements put the onus on the beneficiaries, thereby increasing the amount of variables required to ensure effectiveness.

A better understanding of behavioural factors may be critical to help understand how to best inform POU design and implementation to achieve the greatest impact and effective scale (Clasen, 2009; Fiebelkorn et al., 2012; Waddington et al., 2009). A growing body of evidence suggests that public health interventions requiring behaviour change are more effective when grounded or analysed within a theoretical base(Glanz and Bishop, 2010). There is no consensus on a unifying theory of behaviour change, however, and a wide range of competing frameworks and models exist, often specific to their particular fields of interest(Aunger and Curtis, 2010). A range of theories is used in public health interventions, though it is a relatively recent and growing area in the field of water, sanitation and hygiene (WASH) (Fiebelkorn et al., 2012).

Three recent systematic reviews provide guidance on key lessons from and gaps in the evidence base (Dreibelbis et al., 2013; Fiebelkorn et al., 2012; Hulland et al., 2015). Hulland and colleagues' reviewed factors related to sustained adoption across different WASH interventions (Hulland et al., 2015). They identified several cross-cutting factors that are also found in POU-specific studies, including: interpersonal factors and social norms relating to family, community members, and implementing agents (Schlanger, 2012; Wood et al., 2012); the perceived need to engage in the behaviour and the perceived risk if it is not conducted (Doria et al., 2009; Inauen et al., 2013; Lilje et al., 2015; Olembo et al., 2004); self-efficacy, or confidence in the ability to perform the behaviour change (Mosler et al., 2010); cost and durability of the technology used (Wood et al., 2012); socioeconomic and demographic considerations (Freeman et al., 2012; Komarulzaman et al., 2014; Sheth et al., 2010), and pre-existing habits or experiences related to the behaviour (Lantagne and Clasen, 2012).

Fiebelkorn and colleagues' (2012) critical review of the POU-specific behaviour change literature underlined the general paucity of evidence, and were only able to include 2% of all identified papers(Fiebelkorn et al., 2012). They identified several areas to improve the generally low quality of identified studies. They noted the bias in self-reported outcome measures (Lilje et al., 2015; Mosler et al., 2010), and the weakness of proxy behavioural outcomes (e.g sales to monitor actual usage)(Harshfield et al., 2012), suggesting that studies employ longitudinal, repeat measurements using more objective adherence outcomes. They underlined the benefit in evaluating findings from a behavioural perspective, and using one or more theories to inform the design and analysis of findings(Fiebelkorn et al., 2012). They also noted the value in using formative research and qualitative methods to survey findings to provide a more complete picture of behaviour change (ibid).

Dreibelbis and colleagues' systematic review of WASH-specific theoretical models found the roles played by the primary intervention hardware and environmental factors to be under-represented, that the majority of factors centred around individual-level determinants often rooted within psychological concepts, and noted the importance of identifying the multiple levels that influence behavioural outcomes – of which an intervention may only address one or two. Their findings are further supported by other reviews(Aunger and Curtis, 2010; Fiebelkorn et al., 2012), and were used to develop the Integrated Behavioural Model for Water, Sanitation, and Hygiene (IBM-WASH)(Dreibelbis et al., 2013). The IBM-WASH framework aims to present a more balanced framework, focusing on three key dimensions related to Psychosocial, Contextual, and Technological considerations, each of which can operate at five aggregate levels: societal, communal, household, individual, and habitual (ibid). It can be easily adapted to different studies' foci, and does not require stringent adherence to specific constructs(Mosler, 2012), but rather reflective of the complex set of determinants that influence behaviours within a specific context and has been used successfully in a recent studies (Hulland et al., 2013; Najnin et al., 2015).

This paper explores correlates of behaviour change from a longitudinal, mixed methods crossover study of short-term adherence to two POU flocculant-disinfectant, or coagulant disinfectant products (CDP) in Zambia and Pakistan. The study employed a weekly quantitative survey measuring observed longitudinal sachet usage and select covariates, supplemented by focus group discussions, semi-structured interviews, and field observations. Quantitative analysis focused on an exploratory evaluation of potential correlates of adherence, covering a range of potential determinants based on a review of the WASH-specific behaviour change literature. No *a priori* assumptions were held about the relative weight of various factors that might affect adherence. Descriptive findings, exploratory analytical findings, and qualitative findings were triangulated, and critically assessed in light of the WASH-specific behaviour change literature, with a focus on the IBM-WASH framework.

6.2 METHODS

6.2.1 Study design

See Appendix B for an abridged version of study implementation that will be used in the published version of all three results chapters in this thesis, and Chapter 3 for further methodological details.

6.2.2 Data analysis

We triangulated findings from descriptive summaries and exploratory regression analysis from survey responses, as well as qualitative feedback and observations. Each of these elements was analysed separately and assessed collectively, including in light of WASH-specific behaviour change theory, with particular weight given to the IBM-WASH framework (Dreibelbis et al., 2013). However, our analysis did not test a specific hypothesis related to a particular behaviour change framework, but aimed to maintain an open, exploratory perspective.

6.2.2.1 Quantitative analysis

A range of covariates was included in the survey for both descriptive and regression analysis, based on a review of the WASH and POU behaviour change literature, as well as on observations during pre-testing. They were divided into eight broad categories (Table 6.1), though only by way of summarizing the questions collected. These groupings had no bearing on the analytical approach, which weighted all variables equally. Tables 6.3 and 6.7 outline individual questions within these categories for each country study.

Exploratory regression: Our regression modelling methods were primarily informed by the methods outlined by Heeringa and colleagues (2010). Used sachets per repeat visit were employed as the primary quantitative outcome in this study, clustered according to repeat visits within households. A zero-inflated negative binomial regression model (hereby referred to as "zinb") best fit the Pakistan dataset, and a negative binomial regression (or "nbreg") model was employed for the Zambian dataset. The primary outcome for nbreg models was reported in incidence rate ratios (IRR), representing the average rate of weekly sachet usage aggregated over all visits per household. Every outcome for a given independent variable in the zinb models was associated with two components: IRRs for all positive integers (i.e sachet counts ≥1), and odds ratios (ORs) comparing the odds of 0 sachets to ≥1 sachets (i.e.

representing the odds of no sachets being used, reported as "non-usage" in this manuscript). Adjusted Wald's tests were used to assess the overall significance of both components in zinb models.

Potential covariates from the list in Table 6.1 were included in regression analysis if answered by no less than 90% of all respondents and if no more than 90% of responses were in any individual variable category (those not included were discussed in descriptive findings). Furthermore, a theory-based assessment of potentially collinear variables was used to include only unique potential predictors.

Regression models included three *a priori* factors to account for the study design: crossover period (four visits per period), product allocation, and days-between-visits (accounting for discrepancies in the days between individual households' visits due to field logistics). This base model was first used to conduct "univariable" modelling (that is, testing one independent variable in addition to three *a priori* variables). Multiple parameter Wald's tests were used to assess the predictive value of individual variables, and a cut-off margin of 10% (i.e $p<0.1$) was employed to consider independent variables to be indicative of potential significance to the outcome at univariable level. All factors that fit within the more conservative significance level of 5% ($p \leq 0.05$) were included in a multivariable model. A more restrictive inclusion criterion ($p \leq 0.05$) was employed to test the significance of each variable in this model, and a process of backwards elimination followed, including assessments of interactions and potential collinearity until the most parsimonious model was obtained.

Descriptive results: Descriptive results in this paper focus on assessing the central tendency in responses that provided supplementary information to regression findings, including: product feedback, water-related practises and risk perceptions, and reported drivers and barriers. Most of these findings were based on feedback to questions that allowed multiple responses, and where most respondents gave the same response (affecting their ability to be used in regression). Responses to questions with multiple options are reported where they accounted for more than 5% of respondents.

6.2.2.2 Qualitative analysis

The methodology adopted for the design, implementation, and analysis of the qualitative research component was based on Green and Thorogood (Green and Thorogood, 2013) and Creswell and Clark (Creswell and Clark, 2007), with additional details from a RAND

Corporation training manual specific to FGDs and SSIs (Harrell and Bradley, 2009). This paper only presents a portion of the post-survey qualitative findings, focussing on positive and negative product feedback. The emphasis was on obtaining breadth of information, on assessing majority and minority views, and on whether feedback was confirmatory or deviant to questionnaire findings. A relatively deductive approach was taken, based on framework analysis as outlined in Green and Thorogood (2013). English transcriptions of recorded FGDs and interviews, key observations by a dedicated note-taker present at each session, and field notes were assessed by the lead investigator. Feedback was summarized according to the main concordant and discordant responses, the frequency and popularity of given responses, and representative quotes. Qualitative data was used to expand upon quantitative findings, including in a way that might provide a different and divergent interpretation. Qualitative and quantitative findings were consolidated post-analysis following Creswell and Clark's definition of triangulated designs, and specifically, convergence models (Creswell and Clark, 2007).

Table 6 1 [1] Overview of variable categories assessed in regression models

CATEGORY	OVERVIEW
SOCIO-ECONOMIC	Household level education, wealth, and other demographic factors
SOCIAL DYNAMICS	Questions assessing the role of household and social groups on usage
HYGIENE AND SANITATION	Access level, type, and quality, focusing on hand-washing and latrines
PAST WATER RELATED EXPERIENCES & HABITS	Household history of water-related health issues, and treatment practises in childhood of head of household or primary caregiver
CURRENT WATER-RELATED HABITS	Details surrounding household consumption of treated and untreated water, and typical other treatment practises employed
PRODUCT FEEDBACK	Asked for each product at the end of each period, including trust, attitude, preference, perceived safety
HEALTH	Self-reported health outcomes, focusing on diarrhoeal disease

[1] In addition, one question on seasonal effects was included in Pakistan, based on the experience in Zambia

6.3 RESULTS

6.3.1 PAKISTAN CASE STUDY

6.3.1.1 Descriptive findings

See Section 4.3.1.1 and Appendix D (Table D1) for an outline of descriptive findings that will be used in the published versions of this chapter, supplemented by the following additional information: The community was divided into six neighbourhoods distinguished by a form of caste system delineated by physical boundaries and exhibiting distinct social characteristics (some households rarely left their neighbourhood or interacted with others). Weekly household usage (averaged over each crossover period) dropped from a median of 9 sachets per week in the first month to over 5 sachets per week in the second. This drop was most significant as soon as the crossover had taken place. Overall, nearly 31% of households reported consuming untreated water alongside treated water, rising from approximately 25 - 36% over crossover periods.

Table 6.2 outlines feedback on water treatment related practises and beliefs, and questions about drivers and barriers. Most households considered their primary water source to be of "medium", or "low" quality. The majority of households believed that water should be treated based on circumstantial need as opposed to daily or habitually, and all major sources were also consumed without any prior treatment. At the same time, households also listed their own primary sources among the "least safe" sources. Simple cloth filtration was the major treatment method employed, over a quarter of households used natural alum rocks on an occasional basis to reduce turbidity, and over a third occasionally boiled water.

Self-reported drivers and barriers were reported at the end of each crossover period. By the end of the study, 52% of households stated preferring PoW to Pureit, 39% preferred Pureit and the remainder liked both equally. Product satisfaction was similar between products, but dropped in the second month of the study, from 71% respondents giving ratings of 8 -10 (out of 10), to 45%. The main reported reasons to treat water were related to health, and for a minority, the improved appearance of treated water. The greatest reported driver to product usage was the appearance of water, followed by taste, the hot season, having guests, trust for the team, and health improvements, and family support in relatively even proportions. Treating water was noted as the main way to prevent diarrhoea (over 65% of respondents), and water was considered to be the main cause of diarrhoea (nearly 90% of respondents). The two greatest stated barriers were the onset of winter, and water issues experienced in the second crossover period. Water "issues" consisted of source water issues that took place in the final two visits of the second crossover period. Piped water was sporadically low in quantity and quality for between a few hours to several days, due to river cleaning operations affecting the main community source. Households would supplement their water on such occasions with pre-treated water collected from a nearby industrial treatment plant. Other reported barriers included being "too busy" and having guests (though the latter was also cited as a driver).

Table 6 2 Descriptive summary of water-related practises and opinions (Pakistan)

Characteristic	Distribution (%)	Characteristic	Distribution (%)
Quality of primary drinking water source (n=223)		**Whether water needs to be treated at all (n=223)**	
good	13%	yes	86%
medium	55%		
bad	32%	**When should water be treated (n=223)**	
Least safe sources (n=223)**		on occasion	76%
raw surface	88%	everyday	24%
piped (also raw)	22%		
rainwater	17%	**Reported barriers (n=219) ****	
other	8%	season	42%
bore well	5%	water issues (source)	30%
Safest sources (n=223)**		when busy	23%
water brought by NGOs	40%	guests	16%
private bore well	38%		
bottled	24%	**Reported drivers (n=219)****	
water vendor	21%	water appearance	42%
piped - yard	14%	having guests	16%
piped - hh	10%	trust for team	15%
public bore well	7%	taste	12%
raw	6%	season	11%
Sources consumed untreated (n=223) **		family support	8%
piped - hh	39%	family health	6%
raw	33%	**Why treatment is important (n=223)**	
piped - yard	29%	family health	70%
public tap	26%	children health	17%
Previous water treatment practises (n=223)**		water appearance (good, safe)	8%
Boiling	36%	**Health issue due to unsafe water (n=217)****	
Chemical disinfection - alum	27%	diarrhoea	75%
Simple cloth filtration	82%	other stomach related	63%
What causes diarrhoea (n=222)**		vomiting	52%
water	89%	fever	24%
food	59%	cholera	17%
season	12%		
hands	11%	**How to prevent diarrhoea (n=222)****	
faecal contamination	8%	treating water	66%
bad hygiene	5%	food / medicine	42%
Product preference (n=222)		cleanliness	29%
Pureit	52%	handwashing	16%
Purifier of Water	39%	house hygiene	9%
Both equal	9%	personal hygiene	7%

*** questions with the option to respond with multiple answers. Percentages represent proportion of respondents, and do not add up to 100%*

6.3.1.2 Predictive regression analysis exploring determinants of adherence

Univariable analysis

In total, 32 potential determinants of adherence were tested at univariable level, 10 of which were significantly associated (within $p<0.1$) to average weekly usage after controlling for three *a priori* factors: product allocation, crossover period, and days-between-visits (Table 6.3). Notable groups of variables with little to no significant findings included hygiene and sanitation, reported health outcomes, reported effect of season, and product-related feedback, including stated product preference. Detailed results from the univariable analysis are presented in Appendix H (Table H1 a-b). Factors significant at univariable level were:

- household size
    - increases in members led to greater adherence
- neighbourhood
    - differences were observed across neighbourhoods
- whether households ever practised boiling
    - greater adherence was observed if they did
- the proportion of the household that consumed treated water
    - greater adherence was observed with greater coverage
- whether untreated water was consumed
    - lower adherence was observed when untreated water consumption was reported
- whether the product was additionally used for non-drinking purposes
    - greater adherence was observed if it was used
- whether household members were unified in their product support
    - lower usage was observed if they were not
- whether the main respondent (head of household or primary caregiver) reported having grown up in a household treating water
    - greater adherence was observed if it was reported
- whether anyone in the household had reportedly serious adverse health effects due to water-related issues (including emergencies)
    - greater adherence was observed if it was reported
- rating of water safety after treatment
    - lower adherence was observed with lower ratings

Multivariable analysis

NB: in this section, the asterisk (*) denotes overall p-values from adjusted Wald's tests, while all others are specific to a particular component of the zinb model

All variables that were significant at univariable level except for post-treatment product safety rating were significant within p≤0.05, and were thus included in the first full multivariable model. No significant interaction or collinearity was found at this stage. After a single step of backwards elimination based on adjusted Wald's tests, five variables were found to be predictive of usage, together with the three a priori variables (Table 6.4).

- *A priori* variables

The most significant trend in adherence observed in this study was the sharp and highly significant decrease (p<0.0001*) in the second crossover period. On average households had nearly ten times the odds of non-usage (OR 9.7 p<0.0001) and 25% less used sachets (IRR 0.85, p<0.0001) in the second crossover period. Usage did not differ significantly based on which product was being used (p=0.32). Average usage increased slightly but highly significantly (p<0.0001) with days between visits, as seen in the two per cent increase in used sachet counts (IRR 1.02) and over 10% lower odds of non-usage (OR 0.87).

- Socio-economic

Neighbourhoods were strongly related to differences in average usage overall (adjusted Wald's p<0.0001*) though within categories, only one neighbourhood was significantly different to the baseline group (IRR 1.2, p=0.007, OR 0.35, p=0.003*). A one person increase in household size was associated with a slight but overall significant (p=0.0034*) increase in weekly usage (IRR 1.03 p=0.001, OR 0.96, p=36*).

- Water-related experience

Households in which no members suffered major ill-health due to prior water-related issues (including emergencies) were associated with lower weekly usage overall (IRR 0.88, p=0.005, OR =2.5, p<0.001*). [2]

[2] Assessing *not* having suffered was presented in this way to best power the analysis. It may seem intuitively more appropriate to assess the influence of *having* suffered in prior emergencies, that led to 1.13 times the rate of usage for positive sachet counts, and 40% lower odds of non-usage.

- Current product-related habits

Households that reported consuming untreated water in the past week were strongly related to lower usage (p=0.0002*), with 25% lower rates of average weekly usage (IRR 0.85, p<0.001, OR 1.4 p=0.13*).

- Social dynamics

Households that reported differences within the family regarding attitudes and support for the products were associated with lower overall usage (p=0.033*), notably demonstrating nearly twice the odds of non-usage in the past week (IRR 1.1, p=0.16, OR 1.7 p=0.048*).

Table 6 3 Categories of covariates assessed in regression analysis (Pakistan)

A PRIORI	SOCIO-ECONOMIC	HEALTH	CURRENT WATER HABITS	PAST WATER-RELATED EXPERIENCE	PRODUCT FEEDBACK
Crossover period ***	Neighborhood ***	7 day diarrhoea prevalence at baseline	Use of product for non-drinking purposes in past week(RQ) ***	Having suffered major ill health due to water-related issues(including emergencies) ***	Treatment demonstration (rating)
Product allocation	Household size **	7 day diarrhoea prevalence - end of period 1	Use of boiling water treatment**	Water quality in lifetime	Number of product positive aspects
Days between weekly visits ***	Members who completed school	7 day diarrhoea prevalence - end of period 2	Proportion of household consuming treated water in past week(RQ)***	Regularity of treatment while growing up **	Number of product negative aspects
	Asset-based wealth quintile approximation		Untreated water use in past week(RQ) ***	Household or other family members having suffered due to water	Rating of water safety before treatment
	Proportion of literate adults in household			Usual quality of water	Rating of water safety after treatment*
HYGIENE & SANITATION		**SEASON**	**SOCIAL DYNAMICS**		Product preference
Presence of soap in household		Whether weather/season affected use	Whether household members agree about product or differ**		Product rating (likability)
Type of latrine			How team visits affected use		Would you pay 10Rs per packet
			Product preference of social network		Whether product trust changed with time

*No asterisk: not statistically significant ➔ * $0.05 < p < 0.1$ ➔ ** $0.01 \le p \le 0.05$ ➔ *** $p < 0.01$*

Table 6 4: Multivariable zero-inflated negative binomial regression model of factors associated with adherence (weekly sachet usage), Pakistan

COVARIATE	Predictor categories (% distribution) n*=219	Outcome: Rate of average weekly usage per week (non-zero values) and odds of 0 sachets used per week (for 0 values)				
		EFFECT SIZE**		95% CI	Component significance (p-value)	Adjusted Wald's test (p-value)
Days since last visit	*(continuous)*	IRR	1.02	1.01-1.03	<0.001	<0.0001
		OR	0.87	0.81-0.93	<0.001	
Crossover period	2 (50%)	IRR	0.85	0.8-0.91	<0.001	<0.0001
baseline: 1 (50%)		OR	9.7	4.9-19	<0.001	
Product	Purifier of Water (50%)	IRR	1.05	0.99-1.1	0.13	0.32
baseline: Pureit (50%)		OR	1.02	0.69-1.5	0.91	<0.0001
Neighborhood	2 (28%)	IRR	0.94	0.8-1.09	0.38	
baseline: 1 (12%)		OR	0.9	0.49-1.7	0.74	
	3 (8%)	IRR	1.1	0.94-1.3	0.21	
		OR	0.3	0.067-1.4	0.12	
	4 (20%)	IRR	1.2	1.06-1.4	0.007	
		OR	0.35	0.17-0.7	0.003	
	5 (18%)	IRR	1.09	0.93-1.3	0.3	
		OR	1.02	0.56-1.8	0.95	
	6 (14%)	IRR	0.89	0.77-1.04	0.14	
		OR	0.43	0.17-1.1	0.08	
Household size	*(continuous)*	IRR	1.03	1.01-1.04	0.001	0.0034
		OR	0.96	0.88-1.05	0.36	
Having suffered major ill health due to water-related issues (including emergencies)	yes (25%)	IRR	0.88	0.81-0.96	0.005	<0.0001
baseline: no(75%)		OR	2.5	1.5-4.05	<0.001	
Untreated water use in past week	yes (31%)	IRR	0.85	0.78-0.93	<0.001	0.0002
baseline: no(69%)		OR	1.4	0.92-2	0.13	
Whether household members agree about product	some disagreement (11%)	IRR	1.1	0.96-1.3	0.16	0.033
baseline: all agree (89%)		OR	1.7	1-3	0.048	

**n=households*

*** Every outcome for a given independent variable in the zero-inflated negative binomial models is associated with <u>two</u> components: IRRs for all positive integers (i.e sachet counts ≥1), and odds ratios (ORs) comparing the odds of 0 sachets to ≥1 sachets (i.e. representing the odds of no sachets being used, reported as "non-usage" in this manuscript).*

6.3.1.3 Qualitative findings

This section summarises focus group discussions (FGDs), semi-structured interviews (SSI), as well as field observations by the lead investigator and enumerators. Major findings are included below, supplemented with representative quotes in Table 6.5.

Contextual factors

The community was affected by the 2010 and 2011 floods, and received considerable aid from Oxfam and their local partner, the Research and Development Foundation (RDF) – both of whom were connected to this study. Household responses during SSIs and FGDs included consistent requests for further help in kind, and households were often worried about their responses affecting future aid from RDF or Oxfam. It transpired that most households in one neighbourhood (6) had actually relocated to the community directly after the floods, from another part of Sindh (impoverished but not affected by the floods), specifically in order to benefit from aid. Furthermore, most households were observed being more careful in their answers to survey questions, often believing them to be in some way connected to future aid. Enumerators also observed that households would usually collect water twice a day (morning and evening), but were less likely to treat water in the evening (citing being tired or having less time).

Feedback on water treatment and sources

Most households perceived their water source (river water) to be of low and variable quality, as it was vulnerable to seasonal changes as well as upstream contamination. Notable concerns included contamination from a well-known upstream polluted lake (Manchar lake), and low quality and quantity when the river barrage was raised for cleaning (as observed during this study and further discussed below). At the same time, many households also noted that the need for water treatment was based on circumstantial indicators such as season, taste, smell, or appearance, and not as a matter of course.

Product issues

A number of unexpected issues emerged related to the products, discussed in detail in Chapter 4 and Appendix E, and briefly summarized below. Issues included:

- poor packaging in Pureit that led to some packets being compromised and resulting in unpalatable water;

- insufficient stirring of water during treatment leading to discoloured and partially reacted sachet powder;
- unexpected and sporadic source water conditions affecting both products' functioning (which would typically only last a few hours, before the products would function again);
- source water issues in Pakistan in the second crossover period leading to low water quality and supply. This was sporadic however, adding up to less than a week in total over the entire month. Households often supplemented their water from a nearby plant during these moments.

Stated determinants

Reported drivers: The most commonly reported determinants included the visual appearance of the water, greater trust and social reinforcement by neighbours and family (particularly young children) for the products and project, habituation to product characteristics over time (including taste, smell, and the effort of treatment), and improved health outcomes. Many of these factors helped counter rumours and distrust (discussed below) with time. Households also noted that usage was encouraged by the team's weekly visits, and local community volunteers. Though this was also a source of bias, it was mentioned as a source of habit reinforcement. Some households favourably correlated the taste of treated water to water that was obtained from the nearby plant where free water was obtained when the primary water supply was affected (it was said to be appreciably chlorinated).

Reported barriers: The onset of winter was a central stated reason for the decrease in usage, with households noted that they consumed less water when the weather was cooler, and thus needed to treat less. Another key barrier was the issues with source water quantity and quality in the second crossover period, which led to households relying on water from the nearby industrial site. There were also considerable rumours and related distrust before the study population had developed familiarity with the team and the product. Some negative health outcomes were also reported. These were partially linked to the issues observed in Pureit's packaging and to both products' performance. Finally, a few households mentioned fatigue or being too busy to treat water.

Table 6 5 Overview of key qualitative findings (Pakistan)

THEME	FACTOR	REPRESENTATIVE QUOTES / ANECDOTES / OBSERVATIONS
CONTEXTUAL	Community priorities	"Jobs", "income", "food", and "marriages" were the most common priorities for the community.
	Concern about future aid	Households expressed concern that their "names would be removed from the list" (distribution lists for aid). "Now we have clean water" was commonly followed by "what we need is", and a list of requirements including "kitchens", "food to eat", "roads", and "jobs". Enumerators noted that households would ask about who their survey responses were going to, and tried to change responses related to their socio-economic status in case being considered better off than others might lead to less aid.
GENERAL WATER-RELATED BEHAVIOUR	Conception of regular water treatment	"[t]he whole community treats water with the product regularly… according to our need". Need was often related to "when we feel that water is bad", in turn often linked to how water "looks" "tastes", and "smells". "we drink only river water and due to river water we get diarrhoea, skin diseases"
STATED DRIVERS	Aesthetic aspects of water	The main aethethic point mentioned was the physical appearance: "We trust the product because the water looks clean, and clean water is good for our health". A secondary point mentioned was the "mouth feel" of water, with households noting it felt "light" in the mouth (which is positive, as opposed to water feeling "heavy" – possibly due to suspended solids and organic matter).
	Health	The products (particularly PoW) were widely noted to improve digestion and increase hunger: "[PoW] improved our digestion system and my family and I felt more hunger". Water was associated with many health issues, notably diarrhoea, skin infections, and hepatis. Some less expected health connections to the product were also made by a few households, such as improved kidney functioning, less joint aches, cleaner lungs, and reduced fever.

	Habituation over time	"At the beginning when we drank the water it felt like we were drinking medicine, but with the passage of time we became used to it."
	Trust of the products and the team	"[Team] discussions regarding the problems with the products removed our worries and doubts". "Your talks cleared all the questions we had in our mind." Three of the households that left the study returned in the second crossover period, citing demand from their family members and witnessing their neighbours using the products without any issues. Trust was also improved by an unexpected visit from a team of health workers who came for a one day hepatitis campaign and supported the intervention. A local doctor who was showed the products by a community member also spoke positively about them.
	Support from social networks and community volunteers[3]	"In the beginning we did not use the products, but when we saw others using then we did the same." "When we saw this product has no negative effects on others health we started to use it". "My children and family like it now…[their interest] …is a big reason that I use the product more." "At the beginning we did not like either product but local community mobilizers [urged] us to use them and with time we became more used to treating".
	Other: Using the product for other purposes	Using the product for "cooking" or "making tea" was said to increase usage, as it improved taste.

[3] Community volunteers were locally recruited community members who helped with implementation and acted as a bridge between the community and implementing team. They were typically engaged in work with NGOs that worked in their area.

STATED BARRIERS	Rumours	"When we first saw these products we thought these products will kill us and you want to reduce population…we had no trust on you." "After a few days I heard from people of [another] village that these product will reduce fertility" [The product might be] "addictive like heroine"
	Season	All respondents noted season as an important factor for lower use, drinking more water in the warmer months. Enumerators observed that the colder weather may heightened fatigue related to engaging in this new behaviour
	Other : Family dislike, household size Fatigue	Children were a particular concern in the first few weeks when households feared that the products were dangerous for their health. "when my daughter drank pureit treated water she got sick". Reductions in household size, and family members or guests who disliked the products would also lead to less usage. Households noted feeling "tired" when treating at times. "Due to laziness we also treat water less".

6.3.2 ZAMBIA CASE STUDY

6.3.2.1 Descriptive findings

See Section 4.3.2.1 and Appendix D (Table D2) for an outline of descriptive findings that will be used in published versions of this chapter, in addition to the following: Weekly household usage (averaged over each crossover period) dropped from a median of 6 to over 4 sachets per week over crossover period. This drop was most significant as soon as the crossover had taken place. Overall, 50% of households reported consuming untreated water alongside treated water, rising from approximately 49- 62% over crossover periods.

Table 6.6 summarizes survey responses regarding water treatment as well as reported drivers and barriers. Approximately 58% of respondents stated preferring PoW, 27% Pureit, and the remaining 15% liked both equally. The majority of respondents considered their usual water quality to be good, with standpipe water and piped water in general being widely considered the safest available sources. Standpipe water was also the most common source that was consumed without further treatment. Shallow well water was considered the least safe, followed by raw surface water. Nearly all respondents noted that water should be treated everyday. The main water treatment method that was practised was chlorine disinfection, though, in contrast to responses regarding water treatment frequency, this was practised seasonally by 95% of household. A small proportion of households reported practising boiling, though this was also practised infrequently. Health and taste were each cited as the single main reason to use the products (over 35% of responses each), followed by water quality (under 20%). The appearance of treated water, trust for the product, and what season it was were all mentioned by approximately 15% of respondents. Finally, smell, demand from the family and having guests over were noted by approximately 10% of respondents. Key stated barriers primarily had to do with being too busy or too tired (over 60% of responses). This was followed by situations where water did not need further treatment and was of good quality, which was also connected to the season (the period considered to be most at risk was the rainy season). The majority of respondents (over 90%) noted that diarrhoea was related to contaminated water, and that the main way to avoid it was to treat water (over 75%).

Table 6 6 Descriptive summary of water-related practises and opinions (Zambia)

Characteristic	Distribution (%)	Characteristic	Distribution (%)
When should water be treated (n=197)		Single most important reason to treat (n=192)	
everyday	96%	health	37%
Usual quality of primary source (n=197)		taste	36%
good	59%	quality of water	17%
medium	35%	Reported determinants (n=195)**	
bad	6%	taste	34%
Which sources are the least safe (n=197)**		health	34%
public shallow well	78%	water quality	15%
bore well	65%	product trust	15%
raw surface	11%	water appearance	15%
private bore well	7%	season	15%
water vendor	6%	family demand	11%
Which sources are the most safe (n=197)**		smell	10%
public tap standpost	88%	having guests	7.70%
piped water in yard	26%	Reported barriers (n=197)**	
piped water in house	24%	being too busy	56%
bottled water	13%	when water is good quality	17%
Which sources do you drink from directly (n=197)**		in the "safe" seasons	11%
public tap standpost	90%	being tired	8.10%
piped in house	11%	What would push use when don't want to	
piped in yard	7%	children demand	24%
bottled water	6%	visits	22%
Previous water treatment practices (n=198)** +		if emergency	21%
chemical disinfection	58%	family demand	16%
boiling	14%	(always do, fear of disease, used to taste)	14%
filter	1%	How to avoid diarrhoea (n=195)**	
Health issues associated with water (n=196)**		treat water	76%
diarrhoea	92%	food	52%
cholera	48%	wash hands	27%
typhoid	15%	clean home	23%
other stomach illnesses	13%	clean body	11%
vomiting	12%	proper sanitation practises	6%
dysentery	10%		
What causes diarrhoea (n=196)**		Product preference (n=196)	
water	63%	Pureit	58%
food	61%	Purifier of Water	27%
hygiene	22%	Both equal	15%
sanitation	15%		
hands	12%		
air	5%		

*** questions with the option to respond with multiple answers. Percentages represent proportion of respondents, and do not add up to 100%*

6.3.2.2 Predictive regression analysis exploring determinants of adherence

Univariable analysis

Thirty variables were assessed at univariable level, 8 of which were significantly associated (within $p<0.1$) with average weekly sachet usage after controlling for the three *a priori* factors (Table 6.7). Notable groups of variables with little to no significant findings included hygiene and sanitation, reported health outcomes, questions related to social dynamics, and product-related feedback (including stated product preference). Detailed results from the univariable analysis are presented in Appendix H-1 (Table H2).

Factors significant at univariable level were:

- Household size
    - greater adherence observed with more members
- Primary spoken language
    - greater adherence observed in Bemba- as compared to Njanja-speakers
- Reported concurrent consumption of untreated water
    - lower adherence observed when untreated water was consumed
- Product rating
    - lower adherence observed with lower likability ratings
- Whether product taste acceptability changed
    - higher adherence observed in households who noted that the taste was always acceptable
- Whether the main respondent (head of household or primary caregiver) reported having grown up in a household treating water
    - greater adherence observed if respondent had grown up treating water
- Whether anyone in the household had reportedly serious adverse health effects due to water-related issues (including emergencies)
    - lower usage observed if household reported health effects

Multivariable analysis

Five of the variables tested at univariable level were significant within $p \leq 0.05$, and were included in the first full multivariable model. No significant interaction or collinearity was observed. After removing household size during backwards elimination, four variables remained in the final model (Table 6.8).

- *A priori* variables

The key trend observed in this study was the more than 30% drop in average weekly usage rates in the second crossover period (IRR 0.66 $p<0.001$). A 5% increase in usage per additional day-between-visits was also recorded (IRR 1.05 $p<0.001$). There was no significant difference noted in usage between the two products ($p=0.62$).

- *Socio-Demographic*

A slight increase in adherence was observed with additional household members (IRR 1.03 $p=0.011$).

- *Past water-related experience*

Households where the main respondent (typically the female primary caregiver) reported having grown up treating water had nearly 15% greater average rates of weekly usage (IRR 1.14 $p=0.003$).

- *Current product-related habits*

Using the products for non-drinking purposes such as cooking or washing was related to a 24% greater rate of average weekly usage (IRR 1.24, $p<0.0001$). This was the most significant variable in the model, after crossover period.

- *Product feedback*

Lower ratings of overall product "likeability" were significantly associated to lower adherence across both products ($p=0.0072$), and households that gave the lowest score (0-4 out of 10) were associated with 24% lower rates of weekly usage (IRR 0.72, $p=0.003$) than those who have the highest score (8-10 out of 10).

Table 6 7: Categories of covariates assessed in regression analysis (Zambia)

A PRIORI	PAST WATER-RELATED EXPERIENCE	SOCIO-ECONOMIC	PRODUCT-FEEDBACK	CURRENT WATER HABITS
Crossover period ***	Usual quality of water	Household size**	Treatment demonstration (rating)	Consumption of untreated water in the past week (RQ)
Product allocation	Whether water was poor in lifetime	Main spoken language *	Number of product positive aspects	Use of product for non-drinking purposes in past week (RQ) ***
Days between weekly visits***	Whether head of household grew up treating water **	Proportion of literate adults in household	Rating of water safety before treatment	Proportion of household consuming treated water in past week (RQ)
	Whether household suffered because of water in past *	Asset-based wealth quintile approximation	Rating of water safety after treatment	Do you ever use boiling water treatment
SOCIAL DYNAMICS	HEALTH (self report)	HYGIENE AND SANITATION	Rating of water safety after treatment	Whether product is consumed at a particular time of day
How team visits affected use	7 day diarrhoea prevalence at baseline	Handwashing method	Product rating (likability)**	
How community mobilizers affected use	7 day diarrhoea prevalence - end of period 2	Type of latrine used	Product preference	
Product preference of social network			Whether product taste acceptability changed*	
Whether household trust of project team changed with time			Whether household trust of products team changed with time	

No asterisk: not statistically significant

* $0.05 < p < 0.1$ ➔ ** $0.01 \leq p \leq 0.05$ ➔ *** $p < 0.01$

Table 6 8 Multivariable negative binomial models of factors associated with adherence (weekly sachet usage), Zambia (n=191 households)

COVARIATE	Predictor categories (% distribution) n*=191	Outcome: Rate of average usage per week			
		EFFECT SIZE (IRR**)	95% CI	SIGNIFICANCE (p-value)	Adjusted Wald's test (p-value)***
Days since last visit	(continuous)	1.05	1.04-1.07	<0.001	-
Crossover period baseline: 1 (50%)	2 (50%)	0.66	0.6-0.73	<0.001	-
Product baseline: Pureit (50%)	Purifier of Water (50%)	0.97	0.89-1.07	0.59	-
Use of product for non-drinking purposes in past week baseline: no(45%)	yes (55%)	1.25	1.1-1.4	<0.001	-
Household size	(continuous)	1.03	1-1.05	0.011	
Whether head of household grew up treating water baseline: no(54%)	yes (46%)	1.13	1.01-1.3	0.041	-
Product likability baseline: 8-10 (62%)	5-7 (30%)	0.89	0.8-1	0.047	0.008
	1-4 (8%)	0.76	0.63-0.92	0.004	

**n=households*
*** Incidence rate ratio, representing the average rate of weekly sachet usage*
****Adjusted Wald's tests only used for variables with more than two categories*

6.3.2.3 Qualitative findings

The findings in this section summarise focus group discussions (FGDs), semi-structured interviews (SSIs), and field observations. Major findings are below, supplemented by representative quotes in Table 6.9

Contextual

This study site is well known to local and international NGOs, and community members were familiar with field research activities. The population was mobile, with many households having recently come to the settlement from other parts of Lusaka or other provinces in Zambia. Household members were considerably dispersed in the day due to work and other requirements, between the city centre and other parts of the compound like the main marketplace. Households would often shift within the settlement due to high population pressure and rent costs.

The municipal authorities, supported by the ministry of health and NGOs like Oxfam would lead mobilize resources to chlorinate standpipe water at the point-of-collection in the rainy season, when cholera outbreaks were more common. Households were either provided liquid chlorine, or liquid chlorine was added to water during collection at standpipes (*L Katsi, Oxfam GB Zambia & C Nkunka, District Environmental Health Office, personal communication*). Though the second crossover period took place at the onset of the rainy season, point-of-entry chlorination had not yet commenced, nor were study households found by enumerators to have liquid chlorine at the household[4].

Feedback on water treatment and sources

Respondents were generally satisfied with their primary water source (standpipes). They associated piped water with good and safe water. At the same time, a minority of households also mentioned that piped water could be affected sporadically due to maintenance issues and seepage.

[4] Enumerators were asked to inquire informally about liquid chlorine in the final two study visits, though this was not included in the survey

Responses related to water treatment often appeared contradictory. Every respondent in FGDs and SSIs noted that water should only and always be treated at the household level, ideally with chlorine. Yet when probed differently (often in the same session) households would also report only treating water on a circumstantial basis, mostly based on seasonal considerations, and not treating at all when they were too busy. Water treatment was often associated with cholera outbreaks and the rainy season.

Stated determinants

Drivers: The most commonly reported reasons to treat water included water quality (notably, improved appearance due to turbidity removal), improved health (particularly for children), social reinforcement within the household and wider social networks, as well as trust for the team and the products with time and habituation. A minority of respondents also cited household size as a factor determining how much water was treated.

Barriers: The major reported reasons for lower usage included considerable initial distrust and connected rumours, being "too busy", and the onset of colder weather in the second crossover period of the study. A minority of households noted issues with both products during flocculation/coagulation, and feeling unwell after drinking chlorinated water, as discussed in detail in Chapter 4.

Bias

Several respondents, particularly during the more private SSIs, admitted that adherence may have been exaggerated or biased in several cases. This included falsely reporting treatment, and presenting used sachets and treated water that had not actually been consumed by households. This was supported by enumerator observations.

Table 6 9 Overview of key qualitative findings (Zambia)

THEME	FACTOR	REPRESENTATIVE QUOTES / ANECDOTES
CONTEXTUAL	When water should be treated – including contrasting information from the same households	Practically every respondent noted that clean water was "water treated with chlorine", it should be treated "everyday", regardless of season, and for all household members. However, respondents often also noted that water should be treated "once a day", or "when the Lusaka Water and Sewerage people come in the cholera season" or "November til March" [i.e the rainy season]
STATED DRIVERS	Water quality	Nearly all households noted "how clean the water is [after treatment]", with particular mention of "how clear water looks after treatment". The visual aspect of water treatment appeared to be a strong factor "because you can actually see the dirt coming off". A minority of households noted that the taste was noted to be better than the liquid chlorine (Clorin®), and that product-treated water had a better mouth feel, feeling "lighter" than standpipe water. The products were often referred to as "medicine".
	Health	Water should be treated to "kill germs" and to "improve health". Households readily mentioned the importance of treating water, washing hands, and good sanitation "to avoid disease", and to "reduce diarrhoea", often including phrases such as "water is life". These issues were often noted as being greatest during the rainy season, referred to as "the cholera season" by one respondent. Greater adherence was said to be in households who "really care about their health".
	Trust	"[A]t first we didn't [trust the team] but [a friend] told me to trust you so that's how [it improved]". "we were a bit afraid that maybe you had put things in the water to make us sick until we saw some of you drinking it" Repeat visits helped build a better relationship with the team creating an opportunity to raise questions and assuage any concerns; "it showed me that you were concerned with me and care about me". Other [people from development initiatives] "don't give chance for us to ask questions"

	Habituation	"It had a smell in the beginning but I am used now". "[W]e like them [the products] and have gotten used to them".
	Hard work	"Some people were afraid to use this medicine because they felt it was too much work, but when taking these products you need to be willing to work just as you have taught us to use them"
STATED BARRIERS		
	Rumours	"[M]any people where afraid that maybe you were Satanists". "We did trust but we were a bit afraid that maybe you had put things in the water to make us sick until we saw some of you drinking it".
	Season	The most common explanation for lower usage in the second month of follow-up was that households consumed less water in the colder season and thus needed to treat less water: "in winter we use less water", "we are less thirsty".
	Fatigue	"Some people were afraid to use this medicine because the felt it was too much work," "some are busy or just lazy"

	Bias Exaggerating adherence through more treated water and used sachets than were actually consumed. Concern about giving the "correct" responses to questions	"[W]e knew you were coming so we would make water". However, this was also often noted as being a helpful reminder, helping habituation. "It's true some people will probably make knowing that you are coming"[5]. "I just heard that there were buckets and I was told it's the last day to get buckets so I came". "I don't want to fail" (in interview responses)

[5] Though visits were unannounced, households could see enumerators approaching their area on the day of a given visit.

6.4 DISCUSSION

This study examines correlates of behaviour change from a mixed-methods multi-site comparative POU adherence intervention. Triangulating descriptive survey responses, exploratory regression analyses, and qualitative findings presented a complex interplay between drivers and barriers over time. The major trends in observed adherence included the drop in weekly usage and rise in untreated water over time, the greater weekly usage and lower concurrent untreated water consumption in Pakistan compared to Zambia, and a range of factors that led to relatively greater adherence in certain subgroups of each study site's population. We overview key factors related to this trend before discussing our overall interpretation in light of the wider literature and behavioural frameworks.

6.4.1 Key findings

Overall adherence

Regression estimates indicated 30% lower average weekly sachet usage over crossover period in Zambia, and in Pakistan, 15% lower sachet usage rates and nearly ten times the odds of non-usage in the past week. Adherence did not significantly differ based on which product was being used ($p>0.1$). Furthermore, the drop in usage was most pronounced at the point of product crossover, suggesting that the act of switching products may have also been significant. Low and variable POU adherence is well supported by the current evidence base (Arnold and Colford, 2007; Clasen et al., 2007; Waddington et al., 2009). Reported concurrent untreated water consumption rose over crossover period in both our study sites, and further reduces POU adherence estimates(Brown and Clasen, 2012).

Perceived need and risks related to water

Descriptive survey responses and qualitative feedback suggest that households in both study sites did not traditionally conceive of water treatment as something to be done consistently or exclusively, but rather based on perceived need. Over three quarters of households in Pakistan noted that water should be treated on occasion, basing the key reasons to treat water on physical and time-dependent water characteristics such as taste, smell, appearance, and season. Qualitative findings in Pakistan included reports that "regular" water treatment was when it was treated "according to our need", suggesting a circumstantial appreciation of what "regular" water treatment meant. The second most common reported reason to not treat water in Zambia was when water was already "safe", and when it was in the "safe season" (i.e the dry season). Indeed, seasonal changes were among the top reported reasons in both countries for the decrease in adherence, and are well supported by a number of other studies and reviews (Arnold and Colford, 2007; Olembo et al., 2004; Wood et al., 2012). Wood et al, in their qualitative assessment of drivers of POU adherence in Malawi note that "seasonal and situational patterns…prompt a reassessment of what 'maintenance' means" (Wood et al., 2012). Furthermore, Pureit and PoW were also referred to as "medicine" in both countries, and like medicine, more advanced and intensive water treatment methods (such as boiling, or chlorination) were used as curative, not preventative measures. Thus water treatment in our study may have fallen under Figueroa and Hulme's definition of "purposive" (based on a situational need) as opposed to "consistent" (always treating) (Figueroa and Kincaid, 2010).

Differences in need between country studies

Differences in the perceived need to treat and water-related risks between study sites may also partly explain country-level differences in adherence. Lower perceptions of water quality were observed in Pakistan, and a wider variety of risks were associated with contaminated water across the year. The main water source was surface water from a river with well-documented quality issues (Azizullah et al., 2011; Kazi et al., 2009) that were also observed in our study. Though households noted that this was the main reason for lower usage in the second crossover period, source water issues were sporadic and only adding up to a few days over the entire month. There was also no regularly-used secondary source (the industrial sites water being used on an *ad hoc* basis). In contrast, the primary water source in Zambia (standpipe water) was considered to be of generally good quality, and distinctly preferable to the secondary source (shallow well water) which it had replaced as the primary source in 2004 (UNOSSC, 2005). Olembo and colleagues' assessment of liquid chlorine use in Zambia found that piped water was well-regarded by most households, and that those with access to it were less likely to treat their water than those relying on surface water (Olembo et al., 2004). Water risks were also more time-bound in Zambia (Luque Fernández et al., 2009), mainly associated to government-led standpipe chlorination in the rainy season (though this had not yet started during our study). At the same time, despite positive source-related feedback in Zambia, qualitative findings indicated that many households were aware that standpipe water could be sporadically contaminated, and despite negative feedback in Pakistan, households still reported that water did not need to be treated consistently.

Habits and experiences

Water-related experiences and habits were also observed to be associated with adherence in both countries, and may have further explained some of the between-country differences. Basic water treatment practises were more common in Pakistan where the primary water source was more turbid. The majority of households used simple cloth filtration (i.e setting a towel over ceramic storage containers), and when water was particularly turbid, alum rock. The use of alum, causing flocculation, may have also made households in Pakistan more familiar to CDP products like Pureit and PoW. No regular treatment steps were followed in Zambia, where the majority relied on standpipe water which was low turbidity. Within each country study, regression findings observed greater adherence in households who reported having previously practised water treatment. Households having reportedly suffered ill health due to water-related issues such as cholera outbreaks or other emergency situations were also associated with changes in adherence (though leading to opposite effects in the two countries). The effect of prior water-treatment habits on POU usage has been noted in a number of studies (Harshfield et al., 2012; Hulland et al., 2015; Lantagne and Clasen, 2012). The influence of the past is not commonly collected in the behaviour change literature, but may present valuable context, particularly on habits (Aunger and Curtis, 2010).

Product feedback

Product related feedback presented a complex combination of positive and negative factors, including divergent feedback between qualitative, descriptive, and regression findings. The appearance of treated water was a clear driver in both countries, the turbidity removal helping users feel like they were seeing "the dirt come off". Using treated water for non-drinking purposes, such as cooking or washing, was strongly associated with greater adherence in both countries' regression findings. While it may seem rather straightforward that using the products for non-drinking purposes increases overall adherence, it is not a given. As observed in qualitative feedback, some households who did not like one product for drinking still used it for making tea, and some households who only used it for drinking did not use it for other purposes. On the other hand, using Pureit or the Purifier of Water for other purposes may also have encouraged overall acceptability, including for drinking purposes. Taste and smell were more ambiguous factors, often interchangeably mentioned as positive and negative factors, including being noted as tasting like "medicine" or "bitter". Qualitative feedback suggested that when discussed in a positive light, it was often something households had grown accustomed to over time, and associated with other factors, such as identifying that water was clean. Taste habituation over time has also been found in other papers (Schlanger, 2012; Wood et al., 2012). Our findings suggest that organoleptic properties can be used as indicators for positive or negative perceptions. Doria et al (2009) and Jeuland and colleagues' studies of drinking-water perceptions in Europe and South-east Asia, respectively, both found that taste perceptions strongly influenced risk perceptions (Doria et al., 2009; Jeuland et al., 2015).

Many product-related factors appeared to be weakly associated with adherence. Though product attributes and ratings were a major component to the survey, practically none of the product-related variables were associated with adherence in regression analysis. Furthermore, despite the fact that most households in both study sites noted clear product preferences, no difference was observed in usage based on product allocation. Households were more reserved about providing negative responses in the survey than in qualitative feedback. Qualitative findings indicated that both the products and the project were subject to rumours and distrust, particularly during initial visits. Common fears about the products included them being poisonous, and causing infertility, and were added to fears about nefarious intentions of the project in general. These were partly connected to reported and observed issues in both products' flocculation on a number of occasions, and Pureit's packaging concerns in Pakistan.

Overall, our findings suggest that the least ambiguous factors correlated to adherence had to do with factors directly related to product usage. This agrees with Jeuland and colleagues' (2015) finding that "direct experiences", including flavour, may be more important attributes for drinking-water perceptions than less immediate considerations such as future health risks. The most significant factors related to current product adherence included the use of water for non-drinking purposes, and the concurrent consumption of untreated water. Untreated water was one of the most significant covariates related to lower adherence in Pakistan. While it was proportionally higher in Zambia, the lack of significance in regression models may suggest that it was even higher than reported.

Health

Perceived health improvements were one of the most commonly reported drivers for product usage, though the effect of health on adherence was ultimately unclear. Perceived health improvements were not significantly associated to adherence in either country's regression analysis. Households in both countries showed a relatively high awareness of how health and contaminated water, inadequate sanitation or hygiene practises were correlated. Households also correlated a range of other positive and negative health outcomes to product usage, including improved digestion (particularly strong in Pakistan), changes in malaria, tuberculosis, and fertility. These findings support a growing evidence base on the weak impact of health-related information and perceived outcomes on WASH behaviour change (Curtis, 2003; Figueroa and Kincaid, 2010; Hoque, 2003), though such factors are central to many behaviour change theories(Mosler, 2012; Prochaska and Velicer, 1997; Rosenstock et al., 1988).

Norms

The role of interpersonal factors related to the community, households, and the team was commonly cited in both quantitative and qualitative findings. The differences in adherence found across neighbourhoods in Pakistan, which formed distinct socio-cultural units, may have indicated the role of socially-mediated reinforcement, as found in other studies(Kincaid, 2004). The role of demand within the family, particularly in relation to children's health was commonly supported in both countries' qualitative findings, and households reporting some disagreement regarding the product in Pakistan were found to have lower adherence in regression findings. Qualitative feedback in both countries strongly supported the role of social norms as a driver of usage and acceptability, highlighting its role in building trust for the team and products, creating an enabling environment for adherence, and mitigating initial concerns and rumours. Engagement with the team and other community members reportedly mitigated initial concerns and rumours surrounding the project and products. Interpersonal factors are well covered in the POU behaviour change literature (Hulland et al., 2015, 2013; Schlanger, 2012; Wood et al., 2012). Though these factors did not lead to increases in adherence with time, they may have stemmed lower decreases over time. The fact that adherence in Pakistan was the same across products despite the issues with Pureit's packaging suggests that trust helped adherence from dropping further.

Bias

Considerable evidence of bias in adherence estimates and related covariates was found in both countries. This was despite households being repeatedly informed that they were free to use the products as much or as little as they liked. Our findings suggest that a number of households in Zambia falsely reported and demonstrated usage, while in Pakistan, compliance was higher out of concern for future support. Many households in Zambia were chiefly interested in joining for the supplementary supplies provided with them (particularly storage buckets), while in Pakistan, both communities showed a considerable degree of dependency or interest in aid Oxfam and their partner NGO RDF (who this study's team was considered to be a part of). Furthermore, households in both countries clearly noted that their usage was stimulated by the team's visits, and were considerably more careful in their survey responses than in qualitative sessions. Bias may have been partly responsible for greater adherence estimates in the first crossover period, decreasing with trust and habituation over time, and lower "reactivity" over subsequent repeat visits (Ruel and Arimond, 2002) to yield findings closer to what might be expected without the same amount of follow-up.

6.4.2 Assessment of overall findings

We focussed on the IBM-WASH framework to help evaluate our overall findings(Dreibelbis et al., 2013). We divided our findings between the framework's three dimensions (Contextual, Psychosocial, and Technological) and five levels (Societal /structural; Community; Interpersonal/household; Individual; and Habitual), though we also found that certain factors could be defined in more than one category (Dreibelbis et al., 2013), outlined in Appendix H-2).

Most correlates of adherence in our study fit within the Contextual and Psychosocial dimensions, and within habitual, household, and community levels. The relative weakness of factors related to the Technological dimension was not seen to indicate that the products were unimportant determinants of adherence, but rather, by outlining their conspicuous lack of significance, highlighted the fact that the drive to consistently use either may have been ultimately outweighed by the barriers. We thus surmise an overall rise in adherence-fatigue over time, primarily observed in lower average weekly sachet usage and greater concurrent untreated water consumption. Consistent usage appeared to be something requiring getting "used to" in both countries, and had insufficient immediate and apparent benefits to outweigh the costs. These included the unfamiliar aesthetic characteristics of treated water, and the perceived effort of maintaining treatment over time, contrasting with perceived water-related needs and habits, largely set as community-level norms. A number of additional factors increased fatigue in the second crossover period, including the act of switching products, seasonal change, and in Pakistan, issues with source water. These were not sufficient barriers in and of themselves, but may have raised the threshold for maintenance of water treatment. Some of our findings may also explain the variable and often low adherence observed in emergency POU use (Brown et al., 2012; Lantagne and Clasen, 2012).

Our results highlight the complex nature of behaviour change, with drivers and barriers of different strengths interacting with one another, leading to an overall "decision balance", as discussed in the Trans-Theoretical Model (Prochaska and Velicer, 1997). On the whole, households failed to move from the "action" to the "maintenance" stage of behaviour change, as outlined in the Health Belief Model(Rosenstock et al., 1988). The concept of what "regular" water treatment, or maintenance of the behaviour means, as noted by Wood and colleagues(2012), is a central challenge for POU, and is related to many habitual factors, often at the communal level, which are extremely challenging to change (Figueroa and Kincaid, 2010). Our findings also support Dreibelbis and colleague's contention that the Technological dimension is critical to assess in POU studies, and also agree with Jeuland and colleagues that some of the key factors determining POU adherence may be related to immediate costs and benefits as opposed to less apparent ones (such as future health outcomes) (Dreibelbis et al., 2013; Jeuland et al., 2015). This is underlined by the fact that the few product-related attributes to affect adherence were those related to direct usage, including concurrent untreated water consumption and using treated water for non-drinking purposes. Our results also underline the importance of viewing drivers at different levels of influence. While certain factors like trust and habituation may have improved over time, they were ultimately insufficient to lead to overall increases in usage, though they may have stemmed potentially lower usage. Furthermore similar factors may have operated at more than one level; thus while household-level water-related habits may have led to greater relative adherence in subgroups of each country study's target population, the overall community-level norms and habits were what determined the major trend, which was the overall decrease in adherence over time.

Ways forward

Behavioural interventions may be one way to address the barriers identified in our study, particularly those related to perceptions around water-treatment. However, this is a relatively nascent field and designing an intervention to effectively change such factors may be highly challenging. While a number of POU behaviour change studies have identified perceived need as a factor to change, suggestions are often quite broad, like "knowledge transfer"(Mosler, 2012), and factual "information" campaigns (Lilje et al., 2015). As discussed, basic awareness and information (particularly related to health) were relatively high in our study and have been often to be weak determinants of behaviour change in some studies (Curtis, 2003; Figueroa and Kincaid, 2010). More motivational interventions may be required, addressing more complex factors ıncluding more irrational and emotional drivers of behaviour (Aunger and Curtis, 2013; Curtis et al., 2009). Approaches using motivational interviewing and lessons from behavioural science such as "nudges" may show promise (Luoto et al., 2014; Thevos et al., 2000). However, such interventions are also likely to be highly time-, implementation-, and cost- intensive, and particularly unfeasible in short-term settings, or for poorly funded projects.

The challenge of changing deep-set behaviours related to water treatment habits and perceptions has been noted in reviews of the POU evidence base (Clasen, 2009; Figueroa and Kincaid, 2010), leading to the suggestion that focusing on the other key element identified by our study – the technology – may be another, and potentially more successful route towards increasing adherence. Addressing factors related to product design and marketing to reduce perceived costs while increasing immediate perceived benefits may be clearer, more easily achievable goals than attempting to change more nebulous and deeply set habitual and normative perceptions of risk, need and safety. Further research on alternative methods requiring lower effort while increasing the likelihood of adequate compliance may be promising (Günther and Schipper, 2013; Kremer et al., 2011; Pickering et al., 2015). Within the context of our study, adherence to CDPs in short-term usage (particularly emergencies) might be optimized by reducing the scope for fatigue, using intensive follow-ups and social reinforcement, and potentially, organizing a more centralized process of treatment whereby some users would be responsible to provide water for the rest of the population (within neighbourhoods, for example).

6.4.3 Limitations

Other than the evidence suggesting considerable user-bias in adherence estimate, the major limitation in our study was the fact that the survey design focused on measuring adherence and field performance during repeat visits (Chapter 4 - Chapter 5) and not to test a specific behavioural framework. Furthermore our selection of potential covariates was based on a wide literature review, and factors were included for descriptive and regression analysis post-hoc. Covariates were not all designed in the same manner (e.g all on a Leikert scale) and limited our ability to conduct further analysis such as structural equation modelling to examine interactions between determinants, or to use principal components analysis to form compound variables from individual ones. Our findings are thus only broad indications of trends, only represent the variables we investigated, and do not represent wider behavioural constructs. Our conclusions within the IBM framework may have been different had more factors been included, which would have affected the relative importance of various findings. The qualitative component of this study was relatively minor, and collected using rapid methods aimed at breadth as opposed to depth, and are thus also indicative. Several factors may have made usage higher than it would be in a non-study setting, including frequent follow-ups, testing water samples, the distribution of all necessary supplies to treat and safely store water, and the fact that products were given for free. Members for qualitative research were chosen to represent a wide range of views on adherence and product-feedback, but selection may have been biased as it was performed by enumerator observations, not objective measures. The lead investigator was more accepted in the Pakistani study site, and able to collect richer data as he spoke the national language fluently, in contrast to Zambia, where he needed to limit his presence during fieldwork to reduce potential bias due to widespread suspicion of foreigners.

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Chapter 7. Discussion

7.1 SUMMARY OF FINDINGS

7.1.1 Field performance

The objective of Chapter 4 was to assess the field performance of PoW and Pureit in the context of short-term implementation and uptake. It was hypothesized that Pureit would have a lower chlorine residual profile than PoW, lower organoleptic properties, and be preferred by users. Field performance was assessed based on product-related survey feedback, water quality findings during repeat visits, as well as qualitative feedback and field observations.

Major findings:

- Water quality differed significantly between the two country studies. Water samples reportedly treated with either product left considerably higher residuals, and met guidelines more consistently in Pakistan than in Zambia. Pureit-treated water had higher chlorine residual concentrations than PoW overall, particularly in the first two hours after treatment.

    - Approximately 52% of all study visits in Pakistan, and 22% in Zambia recorded water samples with free chlorine (F.Cl) within minimum WHO-recommended concentrations for safe drinking-water (0.2mg/l). This represents the proportion of exposure time where "safe" water samples was observed, and is termed "effective use" in this thesis.
    - Water treated with either product in Pakistan was safe from recontamination for the first 12 self-reported hours since treatment, with F.Cl concentrations meeting WHO (0.2mg/l) and SPHERE guidelines (0.5 mg/L) for water treatment in emergencies, though failing to meet CDC emergency guidelines requiring minimum F.Cl levels remaining up to 24 hours post-treatment (CDC, 2000; Sphere Project, 2011; WHO, 2011a).
    - Both Pureit and PoW only delivered safe water for the first 6 self-reported hours since treatment in Zambia, which would be considered unacceptable according to CDC, WHO and SPHERE guidelines (ibid).

    - The median free chlorine residual level in all samples was 1.1 and 0.8 mg/l for Pureit and PoW in Pakistan, respectively, and 0.3 and 0.2 mg/l for Pureit and PoW in Zambia, respectively. Pureit-treated water samples had higher F.Cl and total chlorine (T.Cl) residuals on the whole, though they also exhibited faster rates of residual decay than PoW. Pureit was significantly more likely to have higher free chlorine residuals than the CDC taste-acceptability upper bound (<2.0mg/L), particularly in Pakistan. Nevertheless, PoW-treated samples maintained the minimum average F.Cl levels as long as Pureit in both countries.

  - Pureit may also have had weaker buffering capabilities than PoW. The difference between Pureit and PoW samples at pH levels of 8 and above was stronger in Zambia (61% vs 35% of samples, respectively) than in Pakistan (15% vs 4%, respectively).

  - The presence of water samples and the presence of guideline levels of free chlorine also varied within households over individual visits within crossover periods, most significantly in Zambia.

  - Water quality was hypothesized to be correlated to adherence as well as the accuracy of reported treatment. One way of measuring this was to assess "verifiable use" – the proportion of reportedly treated samples with detectable T.Cl – which was over 90% in Pakistan compared to 60% in Zambia. Approximately 80% of all reportedly treated samples in Pakistan had F.Cl levels above 0.2mg/l, compared to 46% of all samples in Zambia.

- Qualitative and descriptive survey feedback provided important supplementary information to water quality findings.
  - Product feedback indicated greater reported preference for PoW than Pureit. The main perceived differences between the products included Pureit's stronger taste and easier and shorter treatment steps, compared to PoW's lower taste, overall quality of treated water, and longer and more complicated treatment time. Pureit-treated water was also reported to taste stronger with time in both countries, particularly the following day.

  - Both products' performance was affected by unexpected factors on a number of occasions in both countries:

- Poor packaging in Pureit led to perforations in some packets resulting in excessive chlorine concentration for long periods of time, leading to unpalatable water, most notably in Pakistan
- Insufficient stirring of water, leading to discoloured and partially reacted sachet powder, particularly for PoW, and mostly observed in Pakistan
- Unexpected and sporadic source water conditions (typically lasting a few hours or less) may have affected a minority of samples treated by either product in both countries, leading to incomplete flocculation and coagulation
- Source water issues in Pakistan in the second crossover period were associated with low water quality and supply on sporadic occasions. Households supplemented their water with pre-treated water from a nearby plant and did not treat their primary source water on such occasions.

- Field results confirmed and elaborated upon findings from a prior laboratory efficacy assessment (Marois-Fiset et al., submitted). These included Pureit's vulnerable packaging, which the laboratory assessment suggested attenuated the chlorine-quenching agent, which was vulnerable to ambient humidity, being hygroscopic (ibid). Pureit was also found to have a relatively low buffering capability, and demonstrated lower microbial log reduction values at pH levels above 8. The study also highlighted Pureit's unique mode of action of spiking chlorine followed by quenching, and found that its chlorine residual profile to be highly variable depending on ambient water conditions (ibid).

Conclusions:

- Conducting a field performance investigation yielded important findings related to field performance, and were a necessary addition to the manufacturer's internal and national-level quality control measures and the laboratory efficacy assessment (Marois-Fiset et al., submitted).
- Field performance may have been affected by several factors, many of which are not captured by the simple metrics and measurement techniques often used in POU monitoring and evaluation assessments (WHO 2012).

- POU field performance seems particularly prone to changes over time and to the level and quality of usage. Country differences may have been due to a combination of source water and adherence differences.
- Our findings suggest careful pre-testing, training, and implementation of POU methods in short-term settings, particularly complex methods such as CDPs.
- Using longitudinal measurements allowed this study to capture differences over time, and including qualitative measurements and user feedback gave greater insight into aspects to performance that are not routinely examined.
- As the first field examination of the Pureit sachet, this study questioned the use of a quenching agent that was unstable to ambient humidity and usage conditions, the value of adjusting the initial dosage in this manner, and its relatively weaker buffering capacity.

7.1.2 Adherence

The objective of Chapter 5 was to assess short-term adherence to Pureit and PoW, and to evaluate a range of commonly-employed adherence measures. Usage was expected to a) reduce over time, b) be higher during exposure to Pureit, and c) be higher within certain subpopulations based on different household-level determinants. We assessed adherence using observed sachet usage (used to calculate daily usage, weekly usage, and per capita consumption), self-reported sachet usage (estimates of daily consumption per visit), water sample availability, and the presence of detectable total chlorine in samples.

Major findings:

Major findings included variable and relatively low adherence, no difference based on product allocation, a decrease in adherence over crossover period together with an increase in reported untreated water consumption, and greater overall adherence in Pakistan than in Zambia.

- Adherence decreased over time in both countries
    - Median weekly usage dropped over crossover period from 9 - 5 packets/visit in Pakistan (a 44% decrease), and 6 - 4 packets/visit in Zambia (a 33% decrease).
    - Untreated water consumption rose from 25 - 35% in Pakistan, and 49 - 62% in Zambia.
    - Water sample availability dropped by over 30% in Pakistan and approximately 13% in Zambia.

- Few households in either study site met minimum daily needs of treated water
    - Median adherence to SPHERE minimum recommended quantities (2.5 L/capita/day) dropped from 100 – 57% in Pakistan (a 43% decrease), and from 57 – 44% in Zambia (a 23% decrease).
    - Actual adherence was even lower in practice given the concurrent consumption of untreated water (not included in the above estimates).
    - These findings suggest that a QMRA-based assessment would register little change in health outcomes in this project.
- Adherence was higher in Pakistan than in Zambia, and possibly more accurate
    - Observed weekly packet usage was 33% lower in Zambia than in Pakistan in the first crossover period, and 20% in the second period. Average daily usage per visit dropped over crossover period from one packet per day to two packets every three days in Pakistan, whereas it was below daily usage in both crossover periods in Zambia.
    - Over 90% of reported samples in Pakistan had detectable total chlorine, indicating the accuracy of reported treatment ("verifiable use"). In Zambia however, only 60% of reportedly treated samples had detectable chlorine, and more detectable chlorine was observed in the second crossover period.
    - While median weekly usage differed between the two countries by one third, half as many households in Zambia had water samples with detectable chlorine during visits (29% in Zambia as compared to 60% in Pakistan, over the whole study).
- Product exposure
    - No significant difference was found in adherence between products across any of the objective adherence measures assessed (weekly sachet usage, daily sachet usage, per capita consumption).

- Objective measures differed greatly from self-reported usage and intention-to-treat.
    - All measures indicated considerably lower adherence than would have been assumed with intention-to-treat (ITT) analysis.
    - Self reported usage was consistently and considerably higher than observed packet usage.
        - Over 80% of observed packet counts were in higher categories of stated usage in Pakistan, with five times the odds of higher stated usage observed from regression modelling. In Zambia, between 65-75% of observed values

were in higher categories of stated usage. Furthermore, stated and observed values were not significantly correlated.

- The most objective and functional measure employed was "observed used sachets per weekly visit". Daily usage was particularly useful to estimate per capita consumption, though it was based on assumptions of constant daily adherence. Water samples were useful to compare with observed packets, particularly to verify the accuracy of reportedly treated samples. However they could not be used to assess usage in-between visits, as used sachets could.

<u>Conclusions:</u>

- Our findings underline the challenge in measuring POU adherence, and in adherence in short-term settings following basic short-term implementation methods (i.e no behavioural component trying to affect adherence). POU usage was sub-optimal in both case studies, and decreased over time.
- POU adherence is complex, and can be highly variable over time. Findings can differ substantially based on the objectivity of estimates, given the potentially important role of bias and assumptions in estimates.
- Households were not safely covered according to international guidelines for short-term water treatment, and were unlikely to be protected from waterborne disease.
- Our findings provide evidence of significant weakness in intention-to-treat analysis, and self-reported outcomes in our study site.
- We recommend careful definitions of adherence, and for adherence measurements to be routinely included in POU studies. Longitudinal assessments of usage, and combining objective measures such as water quality tests and observed usage may present considerably more accurate findings than cross-sectional and single-measurement assessments.

7.1.3 Correlates of adherence

The objective of Chapter 6 was to explore factors correlated to the major trends in adherence observed in both study sites. It was hypothesised that a range of psychosocial, contextual, and technology-related factors would affect adherence at different levels, within subgroups of each country's target population, between the two products, and between the two country studies. Exploratory regression analysis assessed factors associated with observed weekly sachet usage, and qualitative feedback focussed on self-reported drivers and barriers. Findings were triangulated to inform a more comprehensive interpretation, and discussed in light of different behaviour change studies and theoretical frameworks.

<u>Major findings:</u>

The major observed adherence trends included: no differences based on product allocation; a decrease in adherence over time; greater adherence in Pakistan than in Zambia; and differences within subgroups in each study site. We suggest that the following factors were the most correlated to adherence:

- Perceived risk and need
    - Descriptive and qualitative findings indicated that the need to treat water treatment was ultimately purposive in both countries(Figueroa and Kincaid, 2010). Risk and quality perceptions were largely correlated to physical and temporal factors such as taste, smell, appearance, and season. Many of these factors were expressed at a community-wide level.
    - One of the reasons behind greater observed adherence in Pakistan may have been lower perceptions of source water quality (raw surface water), and greater perceived health and water-related risks. The primary source water in Zambia (from municipal standpipes) was perceived to be of relatively good quality, and water-related risk was mostly considered to be during the rainy season when liquid chlorination took place at the standpipe-level.
- Water-related experiences
    - Households that reported practicing some form of recognized POU water treatment prior to the study (e.g boiling) used relatively more than households who did not.
    - Households where at least one member had reportedly suffered ill health due to water-related issues were correlated to greater adherence in Pakistan, and lower adherence in Zambia.
    - Regular use of simple water treatment methods that were not highly microbially effective, like cloth filtration and alum use were commonly practiced in Pakistan, while no regular methods were practiced in Zambia; this is possibly one component of country-level differences.

- Product factors
    - Product-related feedback was complex, with divergent feedback from different methods, factors used interchangeably as determinants and barriers, with overall unclear effects on adherence.
    - The strongest drivers for product usage appeared to be immediate and apparent factors such as turbidity removal.
    - Using the products for non-drinking purposes was strongly related to greater adherence in both countries.
    - The concurrent consumption of untreated water was strongly related to lower adherence in Pakistan, though not in Zambia, though it was proportionally higher than in Pakistan.
    - Taste and smell were discussed in both positive and negative light, appeared to be adaptable over time, and could be associated to wider negative and positive perceptions, such as safety or distrust.
    - Quantitative analysis indicated that most product-related factors did not significantly affect observed adherence, including product preferences
    - Qualitative feedback was more likely to include negative feedback on the products and project than the survey, and suggested a level of distrust and rumours, particularly in the first month of the study, made worse by unfamiliar aspects to the products and product-related issues observed in both countries.
- Interpersonal factors within the community and with the team led to increased trust, which may have helped counter negative associations to products and team over time, together with habituation to product usage.
- Knowledge and awareness of product usage, and health risks associated to water were high in both countries, and did not appear related to observed adherence.
- Qualitative findings provided considerable evidence of bias in both countries. Notably, households in Zambia admitted to false reporting and greater reported adherence due to courtesy bias and an interest in the supplementary supplies (e.g buckets, stirring spoons). Responses in Pakistan indicated greater adherence than would be expected under non-intervention circumstances, largely due to concerns about future aid being contingent on adherence.
- Findings were evaluated within theoretical frameworks, most notably, the Integrated Behaviour Model for Water, Sanitation and Hygiene (IBM-WASH)(Dreibelbis et al., 2013). We surmised an overall increase in usage fatigue over time, leading to the decrease in

adherence. A complex interplay between drivers and barriers underlined the concept of a Decision Balance(Prochaska and Velicer, 1997), whereby barriers ultimately outweighed drivers in this study. Important Contextual and Psychosocial factors at the community-level led to concepts of "regular" water treatment as well as perceived needs and risks that were not conducive to high and consistent adherence, even over the short-term. Furthermore, the Technology-related drivers were relatively weak, and the act of water treatment had greater perceived costs than benefits. Certain factors may have led to greater relative usage within subgroups of households, including water treatment habits and interpersonal factors, but the community- and habitual-level barriers were stronger, leading to the overall reduction in adherence.

7.2 CONSOLIDATED RESULTS

This section consolidates select results from Chapters 4 - 6 that reinforce some of our findings.

Bias

Qualitative feedback in Chapter 6 indicated significant bias in both countries, including many households in Zambia having a primary interest in peripheral supplies provided with the products (particularly buckets), while households in Pakistan may have shown higher adherence out of concern for future aid. Chapter 4 found the proportion of reportedly treated samples with detectable chlorine, or "verifiable use", to be lower in Zambia (60%) than in Pakistan (over 90%). Examined together, these findings suggest that Zambian households were more likely to falsely represent adherence and treatment (more false positives), indicating lower "actual" adherence. Adherence in Pakistan was perhaps more accurately measured, but may have been inflated due to courtesy bias and the expectation of more benefits in the future.

Bias in reported treatment of water samples in Zambia may have decreased in the second crossover period, lending support to Arimand and Ruel's (2002) suggestion that "reactivity" or bias lowers with successive visits in repeat-measure trials (Ruel and Arimond, 2002). Qualitative findings in Chapter 6 indicated greater trust and habituation to product usage over time. Lower bias over time is supported in Chapter 4 with the increase in detectable chlorine residuals (i.e greater "verifiable use") and samples with "safe" free chlorine levels in the second crossover period in Zambia, despite lower sample availability. Furthermore, stratifying these findings by product (Appendix X) indicated that the rise in detectable chlorine was most significant in PoW samples (where verifiable use rose from 49-60% of samples) as compared to Pureit samples (verifiable use rising moderately from 63-66% of samples). Examined together with the stated preference for PoW in Zambia in survey responses, this increase may have suggested greater "true" usage of both products in the second crossover period, and most significantly for PoW.

The strong evidence of bias in reported treatment and adherence in Zambia lends further support to the possibility that between-country differences in Pureit and PoW's chlorine residual profiles were due to differences in "true" adherence as well as differences in surface water properties. As discussed in Chapter 4, the fact that source water in Pakistan consisted of untreated river water with well-documented contamination (Azizullah et al., 2011), and consisted of standpipe water maintained by the Lusaka Water and Sewerage Company in Zambia, suggests that greater chlorine demand would have been observed in Pakistan. The fact that the opposite was observed, suggests that bias played a greater role in these water quality differences between countries. Such findings further demonstrate the complexity of field performance measurements for household/individual level interventions.

Product feedback

Product feedback assessed in Chapter 4 highlights the fact that households discussed taste and smell in positive and negative lights, and often interchangeably referred to one product tasting or smelling stronger than the other. This chapter's findings support the lack of any adherence difference based on product-allocation, observed in Chapter 5. The fact that most households nevertheless had clear product preferences, and provided differently ranked attributes, yet most of these factors were poor correlates of adherence as seen in Chapter 6, supports our conclusion that Technology-related factors (Dreibelbis et al., 2013) were relatively weak drivers, and outweighed by barriers.

7.3 STUDY LIMITATIONS AND SUGGESTED IMPROVEMENTS

7.3.1 Limitations

- Study sites
  - This study was conducted in two different settings with prior histories of emergencies. Its findings do no represent what effectiveness or adherence would be like under actual emergencies. It is most representative of short-term implementation in settings with low water quality, a relatively common context for POU studies (Clasen, 2009; Waddington et al., 2009).
  - Selection criteria required sites to be familiar to Oxfam GB and partner agencies; be within daily commuting distance to the local Oxfam GB office; have sufficient households for the study, and a recent history of emergencies. The site selected in Zambia was chosen in the absence of any more suitable sites. Its major weakness was the reliance on standpipe water as the primary source. As observed in Chapter 6, households considered their primary water source to be of relatively good quality. More turbid water, as observed in the main secondary source (shallow wells) might have been more appropriate for a primary water source. On the other hand, the sites we worked in allowed us to examine the role of different source water perceptions and habits in our analysis.
  - The entire community in Pakistan was covered, in a smaller, rural community where the lead investigator (the author) was able to interact directly with the community members given his ethnic background. The much larger, urban community in Zambia required a more widely distributed randomized selection of households, which, among other factors, may have reduced social support.

- Measurements
  - The use of longitudinal measurements lent great strength to this study's findings, and weekly follow-ups were chosen to assess any sharp differences in short-term adherence. However the chosen frequency of visits may have been higher than needed for optimum accuracy, as seen in the fact that usage only differed slightly within each crossover period, while being associated with additional bias.
  - Factors determining behaviour change were not designed to fit within a specific theory. Variables were included in the survey in a range of different forms (e.g repeat, non-repeat, nominal, ordinal) and collected at different time points. Though

maintaining an open nature to possible determinants of behaviour change is one of this study's strengths, data could have been collected in a manner conducive to analysis in greater depth and with greater specificity.

- o Chlorine residuals can be affected by several factors in source water. However, microbial and chemical parameters of source water were not assessed due to resource limitations. In the light of laboratory efficacy assessments having already been conducted, we focussed on post-treatment effectiveness; just as urban water utilities rely mainly on chlorine residuals for their water quality monitoring, having recourse only occasionally to the more expensive microbiological examination.
- o Setting findings below 0.2 mg/L as non-detectable when the advertised detection limit of the kit was 0.1 mg/L (see Chapter 3, section 3.1.3.1) may have led to a proportion of false negatives, biasing water quality findings towards non-detectability.
- o Qualitative feedback can be prone to significant bias at various stages, from the design, to the implementation, respondent understanding, and final interpretation (Green and Thorogood, 2013). We aimed to minimize these by following the good practices outlined in Green and Thorogood (2013) and Harrell and Bradley (2009). However, certain sources of bias were inevitable, including the fact that the author was able to mix at ease with the population in Pakistan, obtaining richer data, though also potentially biasing adherence with his presence, and providing a more biased opinion of the study in his own interpretation. On the other hand, the limited exposure to the study site in Zambia may have led to lower quality observations, and an opinion biased towards lower user-interest and acceptance of the study.

7.3.2 Improvements

Improvements to our study design could have included:

- Four biweekly repeat visits over the two months (two per crossover period).
- A site in Zambia with lower quality, higher turbidity primary water (e.g surface water)
- Equally sized communities, or similar forms of selection and coverage in both communities.
- A more explicit inclusion of behaviour change theory in survey design, focussing on assessing constructs in the IBM-WASH model, and designing questions in a more uniform method to ease exploratory analysis of determinants (e.g using identical rank scores to

enable structural equation modelling). Covariates could have been less spread out across repeat visits.

- A greater focus on qualitative methods, including:
    - A more "process" oriented examination (Aunger and Curtis, 2010), of implementation components that affected behaviour change positively or negatively (e.g community discussion activities performed in light of packet issues, or how trust was built to counter rumours)
    - Employing methods such as "projective techniques", e.g word or pictorial association exercises that aim to draw out more subconscious, emotional drivers (Aunger and Curtis, 2015). Another use of such activities might have been asking households to describe what ideal water treatment would be; the format employed in this study led to simple and biased responses to this question, particularly in Zambia where households simply cited the intervention products as the ideal water treatment method, conflicting with other findings (Chapter 6).
- Assessing source-water quality, including pH, turbidity, and microbial indicators over a number of time points over the duration of both studies to better characterize field performance.
- A return to the study site several months after the end of the crossover study to assess sustained usage, and even twice in the first month to assess short term usage.
- A larger sample size. This could have allowed us to examine different categories of adherence as outcomes, and probe correlates of high, medium, and low adherence, for example.

7.4 IMPLICATIONS FOR FUTURE RESEARCH AND IMPLEMENTATION

This section discusses some of our findings' implications and suggestions for further research and implementation, many of which were touched upon in each chapter's conclusion.

Pureit

This was the first field assessment of Unilever's Pureit sachet. Recommendations were also provided to Hindustan Unilever's Pureit ® brand team. The many issues identified included Pureit's inadequate packaging, reagents that were unstable to ambient humidity, and weaker buffering, leading to our overall recommendation for Oxfam to not employ the current form in their operations. Our key recommendations to the manufacturers were to make the packaging more robust to handling, improve the product's buffering capability, while focusing on the more streamlined process – its main comparative advantage. We also questioned whether the spiking- and quenching- activity was necessary, which complicated the packaging process (requiring splitting the quenching and disinfecting agents, noted to be troublesome by some respondents); used a quenching agent that was unstable relative to ambient humidity; and did not provide water that was noted to have lower organoleptic properties. Furthermore, the product did not maintain water safety for longer periods of time than PoW.

Aesthetic properties and immediate benefits to water

Our water quality findings also raised questions about the mechanism and role of organoleptic properties, as well as wider questions about what perceptions are of the most importance to POU product choice and adherence. We hypothesize that organoleptic properties, within limits, can be subject to habituation, and can be used as indicators or markers of wider positive and negative perceptions. Jeuland et al's (2015) contention that immediate level factors are more important than less immediate factors is in line with some of our findings, and may also explain why health outcomes, which are not immediate nor necessarily implied, may be weak determinants of adherence (Figueroa and Kincaid, 2010; Jeuland et al., 2015). Deeper investigations into these matters could help elucidate what really matters to POU design from a user perspective. There is also scope for studies focusing on the chemical aspects of water treated with various POU processes and their potential effect on perceived organoleptic and other aesthetic qualities. One specific example derived from our findings would be to examine whether and how free chlorine concentrations are related to taste, and what other compounds are involved, including chlorophenols and chloramines (Bruchet et al., 2004; McDonald et al., 2009; Piriou et al., 2004).

Coagulant disinfectant products

CDP products are among the most efficacious POU products (Souter et al., 2003; WHO, 2002), able to remove extreme turbidity, helminths, viruses, and protozoan oocysts (Souter et al., 2003) making them particularly appropriate for extreme contamination in short-term settings. However, we found subsamples of Pureit- and PoW- treated water in both countries that experienced inadequate flocculation and coagulation in sporadic instances (Appendix X). The issue was known to PoW developers (*A Tummon, Procter & Gamble, personal communication*) who suggested that it may be due to considerably aerated source water. It may also have been due to several other factors related to source water, none of which were controlled in this study. If such issues were observed within our small sample size and short timeframe, they could be more significant in longer term studies implemented at wider scales, which would be particular dangerous in high-risk settings such as during cholera outbreaks. We did not identify similar issues reported in other CDP studies however, which may further underline the importance of including qualitative and usage observations together with water quality metrics in field performance or effectiveness studies. Source water conditions in real-world settings could be further investigated. Further research into CDP designs would also be valuable, particularly focussing on reducing the required effort, such as reducing stirring times and the number of steps. The effort of CDP usage is one of the major reported issues observed in our study, as well as in others (Aquaya, 2005; Clasen, 2009).

Short-term deployment

This study focussed on short-term adherence, which has been suggested to be one of the most promising contexts for POU usage(Schmidt and Cairncross, 2009). The literature on emergency POU adoption and impact is still relatively sparse, and further research would be beneficial. Such efforts would be most effective if conducted with objective measurements of adherence, and mixed methods to obtain user-feedback and perceptions, within the limitations of being in an emergency setting. Such studies could perhaps be easily conducted in relatively controlled emergency-related environments such as camps or provisional shelters.

Effectiveness studies

New POU product assessments

We recommend that future editions of the WHO-led POU guidance material (WHO, 2012, 2011b) include more prescriptive guidance on assessing field performance, potentially as a final step after ensuring efficacy under controlled conditions(WHO, 2011b). This could focus on certain simple field-ready measures such as chlorine residuals, microbial indicators, together with feedback on usability and user concerns (which would have included the packaging issues observed in our study site in Pakistan, for example).

Adherence studies

One of our major recommendations is for monitoring and evaluation guidelines (WHO, 2012) to highlight the importance of adherence estimates, the associated challenges, and relative strengths and weaknesses of various measures. Future case studies and reviews of POU effectiveness and health impact would benefit from including adherence as a pre-requisite factor. Longitudinal assessments are recommended in light of the potentially high variability adherence can display over time, as observed in our study and supported by other reviews (Hunter, 2009; Waddington et al., 2009). We recommend obtaining the most objective outcome measures possible, in light of the considerable weaknesses in intention-to-treat and self-reported outcomes observed in our study, as well as in others(Arnold et al., 2009; Rosa, 2012). We suggest also including measures that allow an assessment of reporting bias (such as combining objective measures of water quality to self-reported treatment). Untreated water consumption is impossible to control, but is critical information to include in adherence estimates, even in the form of self-reported data. Studies using QMRA to investigate water-related risk might also benefit from more accurate real-world adherence measures.

Though better adherence monitoring would be highly valuable to the POU evidence base, the manner and frequency with which data is collected could also affect user behaviour, indicating the need for a balance between measurement accuracy and potential bias. Further research into passive monitoring methods for various POU technologies may have great potential value. It might be possible for filters adherence to be monitored according to flow rates for example, and feedback relayed digitally. This could make a highly significant difference to bias and the quality of monitoring, and could also take place over longer periods of time.

Behaviour change studies

The variable and low adherence observed in our study underlines the critical need for further research into behavioural correlates to POU adherence (Fiebelkorn et al., 2012; Figueroa and Kincaid, 2010). We followed a number of the recommendations made by Fiebelkorn and colleagues (2012) for improved study designs, and support the use of mixed methods, longitudinal objective outcome measures, and theory-informed analysis of findings in future studies. Our study uses strong outcome indicators (particularly as they were longitudinal and objective), the allowing us to be relatively confident about outcome estimates, and to differentiate between levels of effect in a more complex manner than would be possible with a binary outcome, such as self-reported usage(Lilje et al., 2015; Mosler, 2012).

We also suggest the future studies include theoretical constructs in survey design. However, in light of the preconceptions and bias we observed surrounding survey response, as well as the difficulty for users to respond to more complex questions surrounding behavioural motivations, we caution future behaviour change studies that are only focused on survey based analysis, and on relatively complex psychological, individual factors. These findings are a further reason to add qualitative methodsto investigations evaluating perceptions and behaviours.

The POU behaviour change literature focuses more on factors correlated to behaviour change than to behavioural interventions(Thevos et al., 2000). While a modest but growing range of behavioural factors that may inform adherence (e.g perceived vulnerability and risk) are being identified (Hulland et al., 2015), there is relatively little on how such factors can be practically translated into effective behaviour change interventions (e.g what specific messages and implementation styles affect perceived vulnerability). Further research in this area is recommended, particularly from current non-intervention programmatic efforts.

Some of our findings' key lessons for future implementation include the importance of cultivating interpersonal relations, keeping an open communication channel to tackle questions about usage (particularly where complicated methods like CDPs are involved), and involving local community members. Cultivating trust in the products, and encouraging habituation through supplementary use of products for non-drinking purposes is also recommended. However, all of these factors address immediate concerns relating to implementation, as opposed to underlying habits and perceptions regarding water treatment, which may be more important to ensuring adherence.

Changing underlying perceptions related to POU water treatment needs and risks is arguably one of the key challenges for POU behavioural interventions, though it is as yet poorly covered. Further research on health communication within the WASH and POU field may also be useful. The importance of familiarity with water treatment and related habits (Harshfield et al., 2012) might also support "setting the groundwork" by more broad-based community-level communication activities, which could be designed to promote a broad range of interventions within the context of primary health care, for example.

Future directions for POU

Our findings support the growing body of evidence indicating that POU adherence can be highly challenging, even in the short-term. While we acknowledge the potentially important role POU can play in improving access to safe water and related health benefits, our findings indicate weaknesses in many of the products and implementation methods currently employed.

The attitude towards adherence in this study often seemed to be one of having to do something that was a tedious moral obligation, acknowledged to be "good", but insufficiently attractive to be performed consistently. There was a moral dimension, in that all households knew that treating water was "good for…health", and that they should treat water. They would also discuss non-users in negative terms (as being lazy, or ignorant of health benefits). This overall impression may be due to a combination of low technology-centred drives, and implementation methods that typically include a certain moral judgement. This is discussed in Jensen's division of health education into "moralistic" (the dominant mode, focusing on actions to be condemned and promoted), and "democratic" paradigms (focusing on understanding the environment in which behaviours take place, and the target population's conceptions in order to identify how to develop their "action competence" to improve their health) (Jensen, 1997).

Furthermore, POU treatment is mostly developed and implemented following a top-down approach, focusing on the understanding of the developers/implementers, which can lead to interventions and methods that are efficacy- focussed as opposed to user-focussed. A prominent example is the Roundabout Play Pump (winner of the World Bank Marketplace award), widely criticized as an attractive idea with poor impact in practice (Martin, David, 2009; Stellar, Daniel, 2010). Vestergaard Frensen's equally advertised LifeStraw Filter (winner of the product of the year award in 2000), has also been demonstrated to be discontinued, easily broken, and of little practical use given the small quantity of water extracted(Boisson et al., 2010). Moreover, the lack of familiarity with complex POU technologies can lead to dangerous misunderstandings in usage. In our Pakistan case study, a child mixed PoW's powder into a glass of water thinking it was Tang ® (powdered juice), and though he did not sustain serious harm, vomited once and refused to drink treated water thereafter. Some households in Zambia thought the packets could get easily mixed with shampoo, locally available in similar sachets. It is also noteworthy that POU treatment, beyond simple methods such as storage, has little historical precedent as continuously adopted methods. Even though boiling is the main historical POU practice (Rosa and Clasen, 2010) Rosa's study of boiling indicates that even the "regular" practice of boiling revealed variable findings when objectively measured(Rosa et al., 2014)).

We surmise that interventions reducing the effort while maximizing adherence and efficacy might be the most useful POU technologies. In Pakistan, we observed that simple cloth filtration was practised by the majority of households, though this is not an effective method. However, boiling and the use of alum, more effective though also more effortful, were only conducted on a circumstantial basis as well as being perceived and used more "like medicine". The effort required may be central to these perceived differences, leading to the less effective method being used more consistently. We agree with Clasen (2009), and Figueroa and Kincaid (2007) that it may be easier to focus on improving POU technologies rather than attempting to change perceptions around pre-existing methods and situations (Clasen, 2009; Figueroa and Kincaid, 2010). We suggest that the greatest adherence for POU products may come from methods that require low effort and ensure high adherence, while being highly efficacious. Passive disinfection techniques, combined with storage may be among the most promising methods in this regard. Water storage was practised by 100% of participants in our study, and is an essential requirement in settings where running water is not provided at the household-level (Cairncross and Valdmanis, 2006). A number of studies have shown the high degree of adherence observed in safe storage interventions (Ercumen et al., 2015; Günther and Schipper, 2013). Indeed, Ercumen and colleagues found that safe storage was protective with or without additional chlorination (Ercumen et al., 2015). It provides an additional, and in many cases, more valued aspect to drinking-water – highlighted by the appreciation shown for the safe storage buckets provided in our study. Passive disinfection with safe storage could thus be particularly promising. User-centred participatory research could be conducted to identify the best designs, aiming to maximize acceptability (e.g being mindful of traditional methods) and provide as many immediate benefits as possible (e.g aesthetic considerations, storage capacity). This also resembles more traditional water treatment methods, such as the cloth-filtration observed in Pakistan, and traditional methods in the Indian subcontinent such as water storage in pure silver and copper containers, both known for their disinfectant properties (Thurman et al., 1989; Yahya et al., 1990).

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APPENDICES

APPENDIX A: Clearance

A-1: LSTHM Ethics

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LONDON SCHOOL of HYGIENE &TROPICAL MEDICINE

Observational / Interventions Research Ethics Committee

Dr Joe Brown
Lecturer
DCD/ITD
LSHTM

3 August 2012

Dear Dr Brown,

Study Title: **Investigating the acceptability of a point-of-use water treatment device in the context of humanitarian relief settings**
LSHTM ethics ref: **6200**

Thank you for your letter of 1 August 2012, responding to the Observational Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Conditions of the favourable opinion

Approval is dependent on local ethical approval having been received, where relevant.

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	Version	Date
LSHTM ethics application	n/a	09/05/2012
Protocol	V2	15/07/2012
Consent form – FGD		01/08/2012
Consent form – interview		01/08/2012
Consent form – questionnaire		01/08/2012
Pureit questionnaire	V2	17/07/2012

After ethical review

Any subsequent changes to the application must be submitted to the Committee via an E2 amendment form. All studies are also required to notify the ethics committee of any serious adverse events which occur during the project via form E4. At the end of the study, please notify the committee via form E5.

Yours sincerely,

Professor Andrew J Hall
Chair
ethics@lshtm.ac.uk
http://intra.lshtm.ac.uk/management/committees/ethics/

Improving health worldwide

Page **1** of **1**

A-2: Pureit® certification

Hindustan Unilever Limited

Hindustan Unilever Limited
Research Centre
64, Main Road, Whitefield
Bangalore - 560 066

Tel : + 91-80-39830000
Fax : + 91-80-28453086
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TO WHOM IT MAY CONCERN

7 May 2012

Concerning: Pureit sachet for drinking water purification

Unilever's Pureit sachet is a flocculant-disinfectant powder, designed for the purification of drinking water, particularly for sources affected by high turbidity and microbial contamination. Its main active compounds are calcium hypochlorite and Polyaluminum chloride, well characterized chemicals for water treatment, used by several products in the market.

Pureit sachet has undergone more than 1 year of rigorous testing by Unilever's Research & Development team as well as testing by external laboratories and organizations. Pureit sachet meets the most stringent EPA guidelines for anti-microbial efficacy (6-4-3 B/V/C reduction) while removing contaminants like arsenic (300 ppb to less than 10 ppb).

Pureit Sachet has also been given approval by FDA (Food and Drug Administration) which is a trusted agency of Government of India working in the field of upholding safety standards and consumer protection. Hence, it is deemed to be perfectly safe for human consumption.

Pureit sachet has been tested in number of consumer homes in both urban and rural India in 2011. This has been done via various pilots in the States of Maharashtra, Karnataka, West Bengal and Uttar Pradesh in India over a period of last one year.

R Venkataraghavan
Discover Category Leader, Water

Hindustan Unilever Limited
Unilever House
B.D. Sawant Marg
Chakala, Andheri (East)
Mumbai- 400 099

APPENDIX B: Abridged methodology for published versions of chapters

A longitudinal, dual-site crossover study was conducted, focussing on adherence to the Pureit® sachet (henceforth referred to as "Pureit") and Purifier of Water ® (henceforth referred to as "PoW"). The project took place in urban Lusaka, Zambia (n=204 households) between October - December 2012, and semi-rural Sindh, Pakistan (n=233 households) between November 2013 - January 2014, in settings with recent local histories of emergencies (cholera outbreaks and flooding, respectively), though not experiencing any at the time. Primary assessment of the study focused on a quantitative survey, for which a minimum of 200 households were required, powered to estimate a 10% difference in average weekly usage (defined as the presence of detectable total chlorine between treatment groups, α=0.05, β=80%). The main respondent was the primary female caregiver, or if unavailable, another adult involved in water treatment. A sub-sample of households was chosen for qualitative research (focus group discussions and semi-structured interviews) using purposive sampling to obtain a representative group of users.

After door-to-door recruitment and obtaining consent, group demonstrations of product usage were conducted, followed by distribution of the products and ancillary supplies (10L treatment buckets, 12L covered storage containers with a tap, a water-stirring spoon, cotton cloth for filtration, and pictorial flyers underlining usage steps). The total community size in Pakistan approximated the required sample size sufficiently to be included in its entirety (there were no refusals). In Zambia, every eighth household from within a single block, or "zone" of the selected low-income settlement was invited for recruitment, and in the event of refusal or absence, immediate neighbours were approached (2% of households visited refused, reasons stated included a lack of interest, and not being present in the area for the two months of the study).

Half of all participating households were randomly allocated to one of the two products for four weeks ("crossover period 1"), after which they were switched to the alternate product for another four weeks (" crossover period 2"). Four unannounced visits were conducted per month on a roughly weekly basis to assess treated water quality and observe sachet usage. Each sachet treated 10L of water. Oxfam GB expected households to use a minimum of 1 sachet per day, if it were only for drinking-water purposes, and up to 3 sachets per day based on family size and other uses for treated water (*N Bazezew, Oxfam GB, personal communication)*. Households were allocated sufficient numbers of a given product prior to the first visit of each month, and provided more if required. The freedom to use the products as much or as little was clearly conveyed throughout the study, and neither product was strongly promoted.

(Shortened in Chapter 5, excluded in Chapter 6): Enumerators collected and tested samples of any water container that had been reportedly treated with PoW or Pureit within the last 24 hours, at every repeat visit. Samples were tested across four physico-chemical parameters: free and total chlorine, pH, and turbidity. Free chlorine (abbreviated as "FC"), total chlorine (abbreviated as "T.CL"), and pH were all tested using a Palintest Standard Comparator Kit ® (PT 220). Chlorine residual tests were able to detect free and total chlorine from 0.1 – 1.0mg/L (in 0.2 mg/L increments), and from 1.0 – 5.0 mg/L (in 0.5 mg/L increments). The pH test could detect pH from 0 – 14 in increments of 1. Turbidity was measured using a Wagtech ® two-part turbidity tube (Palintest Ltd, UK), with a capacity of 300ml. All chlorine residual tests were conducted in duplicate, and pH and turbidity were conducted once for every sample. The chlorine detection limit of the kit being employed in this study was technically 0.1mg/L, but in practice it was difficult to determine any colour change below 0.2 mg/L. Values <0.2 mg/L were therefore considered to represent non-detectable chlorine residuals. Information on time-since-treatment, container quality, water source, and method of sample provision was also collected.

(Chapters 4 and 6 only:) Qualitative assessments included six post-survey semi-structured interviews (SSIs), 9 post-survey, and two pre-survey semi-structured focus group discussions (FGDs) in Pakistan; 14 post-survey interviews, one pre-survey FGD and two post-survey FGDs were held in Zambia. All SSI and FGD participants signed a consent form. Audio recordings were taken for transcription into English by enumerators, and analysed by the lead investigator together with field notes. Household selection was purposive, focusing on obtaining a range of low - high adherence users, and for FGDs, on ensuring open communication within the group. Enumerators identified households based on their observations during the survey.

Survey data was double-entered in Epidata 3.1 (Epidata Association, Denmark), and analysed in Stata 13 (StataCorp LP, TX, USA). This study was conducted with ethical clearance from the London School of Hygiene & Tropical Medicine Ethics Board, and No Objection Certificates from the Lusaka City Council, and the Office of the Deputy Commissioner in our study district in Sindh.

APPENDIX C: Guidance material informing choice of chlorine levels employed

Disinfection by chlorination is one of the most commonly used POU methods, and a central component of traditional centralized water treatment (Mintz et al., 1995; WHO, 2011). Chlorine is particularly useful given the delivery of "residual chlorine", active compounds that remain after the initial chlorine demand has been met through disinfection, providing a safeguard from future recontamination(WHO, 2011). Chlorine residual guideline value are used in most major water quality guidelines (CDC, 2000; Sphere Project, 2011; WHO, 2011). Monitoring free residual chlorine is useful in field evaluations given that LRVs have been clearly established for given concentrations of free chlorine across many of the major variables that affect the breakdown of chlorine in water, including turbidity, temperature, and pH (WHO, 2011). However, chlorine is also less effective against certain waterborne pathogens, including many viruses and protozoan organisms such as cryptosporidium (it is particularly less effective against cryptosporidium spores, or oocysts) (WHO, 2011, 2002), and chlorine resistant species of bacteria(Baker et al., 2013).

The WHO Guidelines for Drinking-Water Quality recommend a minimum F.CL level of 0.2mg/L at the point of delivery, and an upper-bound F.CL concentration of 5.0 mg/L, a health-based maximum estimate (WHO, 2011). Effective treatment is recommended to yield a minimum F.CL concentration of 0.5 mg/L after 30 minutes' contact time, for drinking-water that is below pH 8 (WHO, 2011). The CDC take palatability into account in their recommended F.CL concentration range of 0.2 – 2.0mg/L, beyond which they consider the chlorine-derived taste to be unacceptable(CDC, 2000). They also recommend that the minimum F.CLl evel of 0.2 mg/L remain so for 24 hours post-treatment. Finally, SPHERE guidelines for water treatment in emergencies recommend 0.5 mg/L F.CL at the tap (which can be interpreted to also mean the point-of-delivery for POU methods), and turbidity below 5 NTU (nephelometric turbidity units). The turbidity tubes used in this study presented findings in turbidity units (TUs). TUs from turbidity tubes can broadly approximate NTUs in field settings, but are subject to significant error considering the simpler method of analysis, varying across researchers, ambient light, and source water suspension characteristics, amongst other factors(Dorea and Simpson, 2011). Typically, 5 or 4 NTU is considered to be the turbidity detection limit of the naked eye (ibid). The greatest error in turbidity tubes is often close to this limit, for values <10 NTU (ibid), and TU findings often differ positively or negatively from NTUs by 5 - 10 NTUs (*C Dorea*, *Université Laval personal communication*).

APPENDIX D: Descriptive tables summarizing community characteristics

Table D 1 Descriptive summary of socio-demographic factors and adherence (Pakistan)

Characteristic	N	%	median (range)	Characteristic	N	%
(blank=not applicable)						
				Main breadwinner occupation	220	
Max number of HHs	233					
Max number of participants	1218 *			Middle		59
Average household size	233		5 (1-13)	Low		32
Gender distribution (female%)	1211*	51		Unemployed/retired		9
Average age (years)	1211*		20 (1-90)			
				Adult literacy (proportion of household)	233	
Median used sachets per visit (both product)				everyone		5
Visit 1	233		10 (0-50)	more than half (less than all)		28
Visit 2	231		8 (0-40)	less than half		67
Visit 3	224		8.5 (0-37)			
Visit 4	222		9 (0-34)	Children school attendance (proportion of households with children)	194	
Visit 5	223		6 (0-50)	None		76
Visit 6	223		5 (0-46)	less than full coverage		18
Visit 7	222		4 (0-38)	full coverage		6
Visit 8	222		6 (0-44)			
Neighbourhoods (n=233)				Primary water source	233	
1	27			In house tap		16
2	66			In yard tap		52
3	18			Standpipe		32
4	46			Secondary water source	136	
5	43			Neighbour pipe		5
6	33			Raw surface water		67
				Local industry water pump		28
Reported daily expenditure PKR (USD approximation)	209					
≤ 200PKR (≤2 USD$)		19				
201-499 PKR (>2 - 5 USD$)		31		Concurrent untreated water consumption	232	
500-799 PRK (>5-7.9 USD$)		31		Crossover period 1		26
≥800 PKR (≥ 8 USD$)		19		Crossover period 2		36

** Total household members (all other N's refer to households)*

Table D 2 Descriptive summary of socio-demographic factors and adherence (Zambia)

Characteristic	n	%	median (range)	Characteristic	n	%
Max number of HHs	204			Main language	204	
Max number of participants	1211			Nyanja		60
Pureit/ PoW distribution		51 / 49		Bemba		23
Average household size	203		6 (2-17)	Mixed		17
Gender distribution (female%)	1211*	51%				
Median age	203		17 (<1-88)			
				Reported daily expenditure ZMK (USD approximation)	198	
Median used sachets per visit (both product)				1000-10,000 ZMK (0.2-1.9 $)		17
1	204		6 (0-47)	10,001-24,499 ZMK (1.9-4.7 $)		35
2	203		6 (0-52)	25,000-34,499 (4.8-6.6 $)		27
3	203		5 (0-64)	≥35,000 (≥6.7$)		21
4	202		6 (0-51)			
5	198		3 (0-23)	Occupation main breadwinner	195	
6	197		4 (0-26)	high level (professional sector)		8
7	198		5 (0-48)	medium level (largely local business)		64
8	198		4 (0-28)	low level service sector		15
				retired / unemployed		13
Adult literacy (proportion of household)	203					
everyone		60		Primary water source	198	
more than half (less than all)		18		standpipe		92
less than half		22		household or yard tap		7
				shallow well water		1
Children school attendance (proportion of households with children)	169			Secondary water source (only used by 42% of households)	120	
less than half		24		shallow well water		95
more than half (less than all)		11		vendor / bottled water		5
everyone		65		Concurrent untreated water consumption		
				Crossover period 1	49	
				Crossover period 2	62	

** Total household members (all other N's refer to households)*

APPENDIX E: Overview of product-related anomalies

Pureit packaging concerns

Within the study's first two weekly follow-ups, complaints began to emerge regarding Pureit sachets. A proportion of households (approximately 20%) alleged that some of the Pureit packets were defective, leading to an unpalatable medicine-like taste, and complaints of throat-ache and diarrhoea in a few children. These issues were accompanied by rumours of nefarious intentions, and distrust. Activities were put on hold for four days to investigate the matter.

Upon inspection, it transpired that Pureit's packaging was susceptible to micro-perforations, as found in approximately 10% of households. Further research, and discussion with the manufacturers revealed that such perforations may have attenuated the chlorine-quenching agent designed to reduce Pureit's initially high dosage to 0.2-0.5mg/l FC. The attenuation of the quenching agent could have led to higher than expected chlorine residuals, as high as 5mg/l, which, though safe according to WHO standards (WHO), may act as a slight membrane irritant (WHO), which could be behind complaints of mild throat ache. Many of subsequent rumours of wider health effects issues are posited to be due to inaccurate causal connections, given the lack of clarity as to what could be expected from the faulty packets. The manufacturers agreed that the only likely adverse effects were due to higher than expected residual chlorine levels.

After evaluating these concerns with all project stakeholders (Oxfam GB Pakistan, Oxfam GB UK, LSHTM, and Hindustan Unilever), it was considered safe to continue the study subject to the community's willingness. These issues were addressed through community discussions held in each study neighbourhood, aimed at clarifying and addressing observed issues, as well as assuaging wider concerns. Households were given the choice to end the study, and chose to continue. They set aside perforated packets, which were replaced, and were given further training on product usage. The discussion was successful, and often mentioned during FGDs and interviews as essential to rebuilding trust and removing wider unconnected fears by clarifying the issues and risks.

"Yellow" water

The team also received reports of some of the packets "going bad"/ not functioning, some packets yielding "yellow" water. Findings of "yellow water" were assessed as being due to insufficient stirring of PoW, which requires longer and more vigorous stirring than Pureit. The yellow hue was the colour of the semi formed, partially coagulated powder.

Figure E-1 Perforated Pureit sachets

Humid content **Perforations**

Right: Pureit sachet in Pakistan, visibly humid, discoloured and sticking to the sachet inside
Left: Seams where perforations were most likely (courtesy C.Dorea)

Flocculation and coagulation issues

The study team came across a third technical issue, reported towards the last two visits of the project. Groups of households sporadically found that water treated with either product would not fully flocculate or coagulate, remaining unsettled in the buckets. Households also noted that water looked and smelled particularly bad on such occasions These reports were on occasions when water was collected at the same time by a group of households, and would usually subside within a matter of hours. This was confirmed by project enumerators, and found to be most probably due to the primary water source in the second month of the study. This period coincided with the annual cleaning of the river, which included raising the barrage, which increased the concentration of upstream contaminants in the water at the point of entry into the community network. Discussions with PoW developers suggested that such coagulation issues may occur due to highly "aerated" water, which is most commonly found in fast moving surface water such as rivers. River cleaning operations may also include additional aeration methods. Water samples were obtained whenever such samples were found, and submitted to the Pakistan Council for Research in Water Resources, who conducted a thorough test of 22 major parameters, though they did not reveal any anomalous findings. On such occasions, many households would travel and collect water from the filtration unit set by the nearby plant as part of community outreach. This water was already chlorinated and households did not further treat it on these occasions. This contributed to lower usage in the second crossover period. Water samples were obtained on three occasions when such samples were found, and submitted to the Pakistan Council for Research in Water Resources, who conducted a test of 22 major parameters, though these did not reveal any anomalous findings.

Figure E-2 Sporadic coagulation issues observed in Pakistan

APPENDIX F: Additional Results Chapter 4

Table F1 : covariates related to water sample maintenance (Pakistan)

Water sample characteristics	Categories	Distribution (%)*
Container	safe storage bucket	98%
Protection	raised covered	84%
	not raised or uncovered	16% (81% of which covered but not raised)
Container state	well maintained	99%
Source	piped and stored river water	95%
Method	no hand contact	99%
Turbidity	≤5 TU	98%

** n=1,159 samples*

Table F2: covariates related to water sample maintenance (Zambia)

Water sample characteristics	Categories	Distribution (%)"
Container	safe storage bucket	94%
Protection	raised covered	79%
	not raised or uncovered	21% (90% of which covered but not raised)
Container state	well maintained	95%
Method	no hand contact	99%
Turbidity	≤5 TU	100%

**n=764 samples*

Table F 3: Somer's D p-values for hypothesis tests of categorical chlorine residual differences over products, visits, crossover period, and time-since-treatment (Pakistan)

INDEPENDENT VARIABLES	Trends in chlorine residual categories: <0.2; 0.2-2.0; >2.0 mg/l)			
UNIVARIATE (stratifications)	Total chlorine (TC) significant difference	Interpretation	Free chlorine (FC) significant difference	Interpretation
PRODUCT	<0.001	Differences between products	<0.001	Differences between products
Crossover period 1	<0.001	Product differences remain after stratifying by phase	<0.001	Product differences remain after stratifying by phase
Crossover period 2	<0.001		<0.001	
CROSSOVER PERIOD	0.34	No difference over crossover period	0.097	Borderline difference over crossover period
Pureit	0.081	No difference over crossover period after stratifying by product	0.96	Crossover differences in PoW samples
PoW	0.94		0.017	
VISITS (1-8)	0.86	No difference over visits	0.048	Differences over all visits
Crossover period 1	0.011	Differences over visits in period 1	0.21	
Crossover period 2	0.98		0.88	
TIME SINCE TREATMENT*	<0.001	Differences over reported time	<0.001	Differences over reported time

** differences in TC and FC residuals were equally significant (p<0.001) over hours-since-treatment after stratifying by crossover period as well as by product*

Table F 4: Somer's D p-values for hypothesis tests of categorical chlorine residual differences over products, visits, crossover period, and time-since-treatment (Zambia)

INDEPENDENT VARIABLES	Trends in chlorine residual categories: <0.2; 0.2-2.0; >2.0 mg/l)			
UNIVARIATE (stratifications)	Total chlorine (TC) significant difference	Interpretation	Free chlorine (TC) significant difference	Interpretation
PRODUCT	<0.001	Differences between products	<0.001	Differences between products
Crossover period 1	<0.001		0.02	
Crossover period 2	0.013	Product differences remain after stratifying by phase	0.006	Product differences remain after stratifying by phase
CROSSOVER PERIOD	0.018	Differences over crossover period	0.004	Borderline difference over crossover period
Pureit	0.30		0.047	Differences over period for Pureit samples, borderline differences for PoW
PoW	0.034	Difference over crossover period only in PoW samples	0.079	
VISITS (1-8)	0.053	Borderline differences over visits	0.004	Differences over all visits
Crossover period 1	0.23	Differences over visits in period 2	0.04	Visit differences only significant in period 1
Crossover period 2	0.032		0.1	
TIME SINCE TREATMENT*	<0.001	Differences over reported time	<0.001	Differences over reported time

** differences in TC and FC residuals were equally significant (p<0.001) over hours-since-treatment after stratifying by crossover period as well as by product*

Table F 5: Product-stratified residual chlorine measures (Pakistan)

MEASUREMENT*	PUREIT			POW		
	Period 1	Period 2	Total	Period 1	Period 2	Total
Self reported treatment of samples	80%	50%	66%	74%	53%	64%
n	455	446	901	444	444	888
Detectable T.Cl in reportedly treated samples ("verifiable use")	90%	93%	91%	90%	93%	91%
n	366	255	591	329	239	568
Minimum safe F.CLin reportedly treated samples	81%	81%	81%	84%	75%	80%
n	366	255	591	329	239	568
Proportion of all households with safe F.CL("effective use")	65%	41%	53%	62%	41%	51%
n	455	446	901	444	444	888
Proportion of all households with detectable T.CL	72%	47%	60%	67%	50%	58%
n	455	446	901	444	444	888

**n= household visits*

Table F 6: Product-stratified residual chlorine measures (Zambia)

MEASUREMENT*	PUREIT			POW		
	Period 1	Period 2	Total	Period 1	Period 2	Total
Self reported treatment of samples	49%	50%	50%	59%	44%	44%
n	403	347	750	377	387	764
Detectable T.Cl in reportedly treated samples ("verifiable use")	63%	66%	64%	49%	60%	54%
n	197	174	371	222	171	393
Minimum safe F.CLin reportedly treated samples	47%	57%	51%	37%	47%	41%
n	197	174	371	222	171	393
Proportion of all households with safe F.CL("effective use")	23%	29%	25%	22%	21%	21%
n	403	347	750	377	387	764
Proportion of all households with detectable T.CL	31%	33%	32%	29%	27%	28%
n	403	347	750	377	387	764

**n= household visits*

Table F 7: Stata output for unstratified logistic regression estimates for the odds of total chlorine ≥0.2 (Zambia)

```
Survey: Logistic regression

Number of strata   =         1                Number of obs      =        733
Number of PSUs     =       189                Population size    =        733
                                              Design df          =        188
                                              F(   6,     183)   =      27.16
                                              Prob > F           =     0.0000
```

cat_tc2	Odds Ratio	Linearized Std. Err.	t	P>|t|	[95% Conf. Interval]	
phase	1.807554	.3726225	2.87	0.005	1.203597	2.71457
phcat3	.816439	.1455559	-1.14	0.257	.5743639	1.160541
hourcat2						
2	.3500614	.160112	-2.29	0.023	.1420028	.8629617
3	.2832524	.1354651	-2.64	0.009	.1102681	.7276077
5	.0333268	.0147408	-7.69	0.000	.013927	.0797496
product	.5074116	.1065311	-3.23	0.001	.3353457	.7677646

Adjusted Wald's test: phase: p=0.0046 ; pH categories: 0.26; product : 0.0015; all categories of time since treatment: p<0.0001. n=households

Table F8: Stata output for unstratified logistic regression estimates for the odds of free chlorine ≥0.2 (Zambia)*

```
Survey: Logistic regression

Number of strata   =         1                Number of obs      =        733
Number of PSUs     =       189                Population size    =        733
                                              Design df          =        188
                                              F(   6,     183)   =      29.94
                                              Prob > F           =     0.0000
```

cat_fc2	Odds Ratio	Linearized Std. Err.	t	P>|t|	[95% Conf. Interval]	
phase	2.183325	.4854774	3.51	0.001	1.408061	3.38544
phcat3	.5603144	.1118398	-2.90	0.004	.3779458	.8306806
hourcat2						
2	.3349116	.1308449	-2.80	0.006	.1549616	.7238297
3	.2615543	.1062428	-3.30	0.001	.1173723	.582852
5	.0230906	.0084757	-10.27	0.000	.0111935	.0476327
product	.4359288	.1013305	-3.57	0.000	.2755967	.6895363

Adjusted Wald's test: phase: p=0.0006 ; pH categories: 0.0042; product : 0.0005; all categories of time since treatment: p<0.0001. n=households

**Variable list: Outcomes: "cat_tc2"= binary T.CL (≥0.2mg/l); "cat_fc2"= binary F.CL(≥0.2mg/l). Covariates: "phase"= crossover period; "product"=product allocation. Phcat3: ph category pH 8-9 vs baseline (pH 7-7.5); "hourcat2_2 - hourcat2-5": categories of time since treatment: 2-4, 5-12, 13+ hours vs baseline (0-1 hours), respectively. Results are odd ratios presenting the odds of detectable F.CLor T.CL.*

APPENDIX G: Additional Results Chapter 5

G-1 Further details on Methods

Crossover-specific analysis (Senn, 2002) overview

This analysis employed total used sachet counts per crossover period per household, and assessed 1) whether there were any differences in the outcome over crossover period (a "period effect") 2) whether there were any differences in the outcome based on the exposure, i.e which product was being used (the "treatment effect"), and 3) whether there was any difference in usage based on when product A or B was provided (i.e Pureit and then PoW, or PoW and then Pureit), which is to say "interaction", "carry-over", or "order" effects (Senn, 2002). These assessments were conducted through a series of two-sample hypothesis tests. Two tests were performed for each of the three aspects outlined above. All tests were T-tests (if the outcome was normally distributed), or Wilcoxon rank sum tests if assumptions of Normality were not met. All differences assessed were within households. Only households that were followed up over all 8 study visits were included in this assessment for comparability.

Period effect tests (effect of crossover period):

- Whether the difference between usage of the two products differed based on the order in which they were allocated. Null hypothesis: total Pureit used sachets - total PoW used sachets did not differ based on the order of product allocation (i.e Pureit and then PoW, or PoW and then Pureit)
- Null hypothesis: Total used sachets crossover period 1 - total used sachets crossover period 2 =0.

Treatment effect tests (how product allocation affected usage)

- Whether the difference between crossover periods differed based on which order the products were allocated. Null hypothesis: usage in period 1 - usage in period 2 did not differ significantly based on the order of product allocation.
- Null hypothesis: Total used sachets Pureit - total used sachets PoW=0

Interaction / carry-over effects

- Null hypothesis: Average usage between Pureit and PoW does not differ based on order of product allocation
- Null hypothesis: Average usage between crossover period 1 and period 2 does not differ based on order of product allocation

G-2: Additional tables

Table –G1: Total sachet measures used in Crossover-specific hypothesis tests (Senn, 2002) (Pakistan)

TOTAL USED SACHET COUNTS / CROSSOVER PERIOD USED IN CROSSOVER-SPECIFIC HYPOTHESIS TESTS		
n=204*	SUMMARY MEASURES	
Total sachet usage - both products combined	Median	Range
Crossover period 1	36	11-72
Crossover period 2	25	0-60
Crossover period difference (1 - 2)	13	-32-56
Total sachet use - separated by product		
Crossover period difference (received Pureit first)	11	-20-45
Crossover period difference (received PoW first)	14.5	-32-56
Avg total used sachets (Pureit)	30	0-62
Avg total used sachets (PoW)	33	0-72
Difference between products	-2	-56-45

** only HHs with complete usage data over all eight visits*

Table G2: Total sachet measures used in Crossover-specific hypothesis tests (Senn, 2002) (Zambia)

TOTAL USED SACHET COUNTS / CROSSOVER PERIOD USED IN CROSSOVER-SPECIFIC HYPOTHESIS TESTS		
n=184 HH *	SUMMARY MEASURES	
Total sachet usage - both products combined	Median	Range*
Crossover period 1	29	3-89
Crossover period 2	20	3-73
Crossover period difference (1 - 2)	8.5	-31-64
Total sachet use - separated by product		
Crossover period difference (received Pureit first)	10	-21-50
Crossover period difference (received PoW first)	7.5	-31-64
Avg total used sachets (Pureit)	23	3-89
Avg total used sachets (PoW)	24	4-83
Difference between products	1.5	-64-50

** only HHs with complete usage data over all eight visits*

Table G3: Litres of water consumed per person per day over time (Pakistan)

Litres consumed	%	n
<2.5L	59	233
2.5-5L	29	
>5L	12	
Average litres treated/person/day	2 (0-33)*	233
-Phase 1	2.5 (0-24)	
-Phase 2	1.4 (0-33)	

median (range)

Table G4: Litres of water consumed per person per day over time (Zambia)

Litres consumed	%	n
<2.5L	75	204
2.5-5L	18	
>5L	7	
Average litres treated/person/day	1.25 (0-28)	204
-Phase 1	1.43 (0-28)	
-Phase 2	1.11 (0-14.5)	

median (range)

Table G5: Odds (OR) of greater observed usage in the event of untreated water consumption (Pakistan)

Outcome: Odds of observed use ≥1 packet /day vs <1packet/day					
COVARIATE	EFFECT SIZE		95% CI	P-VALUE	ADJUSTED FOR
Untreated water consumption	OR	0.74	0.59-0.93	0.009	Crossover period / Product / days-between-visits

Table G6: Odds (OR) of greater observed usage in the event of untreated water consumption (Zambia)

Outcome: Odds of Observed use ≥1 vs <1packet/day (baseline)				
COVARIATE	EFFECT SIZE	95% CI	P-VALUE	ADJUSTED FOR
Untreated water consumption (yes vs no)	0.76	0.61-0.96	0.019	crossover period / product / days-since-visit

Table G7: Comparison of observed and stated categories of daily sachet usage (Pakistan)

OBSERVED			STATED			% Observed values in higher Stated categories
Categories	N (HH visits)	%	Categories	N (HH visits)	%	
0	222	13	0	0	0.5	97%
<1	547	31	<1	113	6	91%
1+	981	56	1+	1676	93.5	98%
Total	1750	100	Total	1789	100	
Categories	Phase 1 (%)	Phase 2 (%)	Categories	Phase 1 (%)	Phase 2 (%)	Pearson correlation
0	4	22	0	0	1	19% correlation
<1	26	36	<1	3	9	p<0.0001
1+	70	42	1+	97	90	
Total	100	100		100	100	

Table G8: Comparison of observed and stated categories of daily sachet usage (Zambia)

OBSERVED			STATED			% Observed values in higher Stated categories
Categories	N (HH visits)	%	Categories	N (HH visits)	%	
0	105	7	0	5	0.5	99%
<1	850	54	<1	395	24.5	75%
1+	615	39	1+	1196	75	77%
Total	1570	100	Total	1596	100	
Categories	Phase 1 (%)	Phase 2 (%)	Categories	Phase 1 (%)	Phase 2 (%)	Pearson correlation
0	6	7	0	0	0.5	2.6% correlation
<1	49	59	<1	25	25	p=0.29
1+	45	34	1+	75	75	
Total	100	100		100	100	

Table G 9: Somer's D p-values for hypothesis tests of observed weekly usage, per capita consumption, total chlorine, and availability of water over products, weekly visits, crossover period, and time-since-treatment (Pakistan)

Independent variables: UNIVARIATE (stratified)	Observed weekly used sachets		Total chlorine presence/absence		Availability of water		Per capita consumption	
	n=233 HH	Interpretation	n=226 HH	Interpretation	n=233 HH	Interpretation	n=233 HH	Interpretation
PRODUCT	0.14	Not different across products	0.99	Not different across products	0.63	Not different across products	0.36	Not different across products
(Crossover period 1)	0.76	No further difference within periods	0.98	No further difference within periods	0.088	Borderline difference in crossover period 1	0.87	No further difference within periods
(Crossover period 2)	0.22		0.85		0.48		0.47	
CROSSOVER PERIOD	<0.001	Different across crossover periods	0.038	Different across crossover periods	<0.001	Different across crossover periods	<0.001	Different across crossover periods
(Product 1)	<0.001	Also different within products	0.12	No difference after stratifying by product	<0.001	Only different in product 2	<0.001	Also different within products
(Product 2)	<0.001		0.23		<0.001		<0.001	
VISIT 1 - 8	<0.001	Different over all visits	0.53	No difference over all visits	0.001	Different over all visits	<0.001	Different over all visits
(Crossover period 1)	0.99	No difference after stratifying by period	0.013	Only different in crossover period 1	0.067	Also different within crossover periods	0.26	Only different in period 2
(Crossover period 2)	0.33		0.85		0.002		0.001	

Table G 10: Somer's D p-values for hypothesis tests of observed weekly usage, per capita consumption, total chlorine, and availability of water over products, weekly visits, crossover period, and time-since-treatment (Zambia)

Independent variables: UNIVARIATE (stratified)	Observed weekly used sachets		Total chlorine presence/absence		Availability of water		Per capita consumption	
	n=204 HH	Interpretation	n=194 HH	Interpretation	n=204 HH	Interpretation	n=204 HH	Interpretation
PRODUCT	0.67	Not different across products	0.006	Different across products	0.41	Not different across products	0.91	Not different across products
(Crossover period 1)	0.45	No further difference within periods	0.009	Only different in crossover period 1	0.017	Difference in crossover period 1	0.34	No further difference within periods
(Crossover period 2)	0.36		0.32		0.2		0.39	
CROSSOVER PERIOD	<0.001	Different across crossover periods	0.049	Different across crossover periods	0.004	Different across crossover periods	<0.001	Different across crossover periods
(Product 1)	0.001	Also different within products	0.56	Borderline difference product 2	0.79	Only different in product 2	0.043	Also different within products
(Product 2)	<0.001		0.056		<0.001		<0.001	
VISIT 1 - 8	<0.001	Different over all visits	0.13	No difference over visits	<0.001	Different over all visits	<0.001	Different over all visits
(Crossover period 1)	0.14	Only different in crossover period 1	0.29	Only different in crossover period 2	<0.001	Also different within crossover periods	0.029	Only different in period 1
(Crossover period 2)	<0.001		0.046		<0.001		0.36	

APPENDIX H: Additional Results Chapter 6

H-1: Further analytical findings

Univariable analysis: Pakistan

In total, 32 potential determinants of usage were tested at univariable level, 10 of which were significantly associated to average weekly usage after controlling for differences between products, crossover period, and days between visits.

- A priori *variables*
  - A sharp and highly significant decrease ($p<0.0001$) in weekly usage rates was observed in the second month of the study, after the products were switched. This was one of the most significant factors in this analysis, with the greatest effect size. A slight increase in weekly usage was also found based on greater days between individual visits. No significant difference was observed based on product allocation, after accounting for the order in which products were assigned. All three variables were kept in subsequent univariable and multivariable models.
- *Socio-economic*
  - Neighbourhood emerged as the strongest predictor within this category. Though the overall multiple parameter Wald's test for this variable was highly significant ($p<0.0001$) only two neighbourhood categories were individually significant, relative to the highest caste neighbourhood: the two lowest income and caste groups. A slight and relatively weak increase in weekly usage was also observed with greater household size ($p=0.043$). Education and wealth did not appear predictive of adherence.
- *Water-related experience*
  - Household members having suffered ill health due to prior emergencies was strongly associated to lower weekly usage ($p=0.0057$), while the head of household having grown up treating water daily, as opposed to infrequently, was indicative of greater usage ($p=0.019$).
- *Current water-related habits*
  - All four questions related to current water related habits were associated to usage. The greatest significance was observed in three repeat questions, asked at every visit. Households in which some members did not use treated

water, and households that reported consuming untreated water in the past week used considerably less sachets on average ($p<0.0001$). On the other hand, households who reported having used treated water for other purposes such as cooking or washing in the past week showed greater usage ($p=0.0003$). Of the questions that were asked at a single time point, households who reported boiling their water at times (mostly on a circumstantial basis), were also associated with greater sachet usage ($p=0.015$).

- *Social dynamics*
    - o Households that did not feel unified on attitudes and support for the products were associated with lower usage ($p=0.034$). Product preference of social groups, or reported relations with the project team were not associated to usage.
- *Product feedback*
    - o Rating water safety after treatment was the only one of the eight variables specific to products associated with usage. Overall ratings dropped significantly in the second month/period of the study, though interaction was not statistically significant. Safety ratings did not affect weekly usage in period 1, and this variable was only of borderline significance overall ($p=0.071$).
- *Other factors*
    - o Hygiene and sanitation factors, reported 7-day diarrhoeal disease point prevalence, self-reported questions related trust over time, and seasonal effects, were not associated to any significant changes in average sachet usage.

Univariable analysis : Zambia

In total 30 variables were assessed within the same construct categories as the Pakistan case study, 8 of which were significant at univariable level. Table 8 outlines the covariates assessed in this analysis, and Table 9 outlines the significant findings at this level.

- A priori *variables*
    - o A highly significant 30% drop in average usage rates was observed in the second month after switching products ($p<0.0001$), together with a 5% increase in weekly usage rates based on each day between visits ($p<0.0001$).

No significant difference was noted in usage between the two products ($p=0.64$).

- *Socio-economic factors*
    - Household size, and primary spoken language, significantly associated with usage. A one member increase in household size (the only continuous variable) was indicative of a 2% increase in usage ($p=0.05$). Belonging to a primarily Bemba-speaking household in comparison to the primary language in Lusaka, Nyanja, was correlated to a 14% increase in usage rates, of borderline significance ($p=0.062$).
- *Past water-related experience*
    - Having previously suffered due to water related issues appeared correlated to 11% lower usage rates, though only of borderline significance ($p=0.08$). Households where the main respondent (typically the female primary caregiver) reported growing up treating water (at all) was significantly associated with 16% greater average usage rates ($p=0.017$).
- *Current water-related habits*
    - Using the products for non-drinking purposes such as cooking or washing, asked upon every visit, was strongly related to a 24% greater usage rate ($p=0.0004$). None of the other questions on water habits were significant.
- *Product feedback*
    - Of the eight product-specific questions assessed, one was significantly associated to usage, and another was of borderline significance. Lower scores of overall product "likeability" rating were significantly associated to lower weekly usage, for both products respectively ($p=0.013$). Households who reported never noticing the taste of the product used more than households who reported noticing it (whether it increased, decreased, or remained the same over time) ($p=0.088$).
- *Other factors*
    - None of the variables related to hygiene and sanitation, reported diarrhoeal disease outcomes, trust for the team or products, or social dynamics were significantly associated to usage.

Table H 1 a) Significant univariable findings (a priori – product feedback), Pakistan

		POSITIVE COUNTS (>0 SACHETS)			ZERO COUNTS (Odds of 0 vs >0 sachets)			
Independent variables	Effect size categories (distribution)	Rate of average weekly usage (IRR)	Category specific p-value	95% CI	Odds of no sachet use (OR)	Category specific p-value	95% CI	Multiple parameter Wald's test
A PRIORI								
Days between visits	continuous (median: 7)	1.02	<0.001	1.02-1.03	0.86	0.001	0.79-0.94	<0.0001
Crossover period (2 in total)	1 (four weeks) / 2 (four weeks)	0.85	<0.001	0.8-0.9	8.8	<0.001	4.7-16	<0.0001
Product	Pureit (50%) / PoW (50%)	1.04	0.15	0.98-1.1	0.95	0.79	0.65-1.4	0.31
n=233								
SOCIO-ECONOMIC	group 1 (20%) baseline							
Neighbourhood	group 2 (12%)	1	0.94	0.87-1.2	1.09	0.77	0.6-2	<0.0001
n=233	group 3 (28%	1.08	0.33	0.93-1.3	0.59	0.37	0.19-1.9	
	group 4 (8%)	1.27	<0.001	1.1-1.4	0.42	0.012	0.22-0.83	
	group 5 (18%)	1.11	0.17	0.96-1.3	1.1	0.76	0.61-0.97	
	group 6 2 (14%)	0.98	0.81	0.86-1.1	0.38	0.038	0.15-0.95	
Household size	continuous (median: 5)	1.02	0.013	1-1.04	0.98	0.59	0.9-1.07	0.043
n=233								
PAST WATER-RELATED EXPERIENCE								
Having suffered ill health due to emergency situations n=220	yes (75%) / no (25%)	0.92	0.076	0.84-1	1.92	0.004	1.2-3	0.0057
Regularity of treatment while growing up n=222	infrequently (63%) / daily (37%)	1.09	0.04	1-1.2	0.65	0.045	0.43-0.99	0.019
PRODUCT FEEDBACK								
Rating of water safety after treatment	0-4 (23%) /5-7 (48%) /8-10 (29%)	0.98	0.76	0.87-1.1	0.63	0.064	0.38-1.03	0.071
(out of 10)		1.07	0.32	0.94-1.2	0.5	0.029	0.26-0.93	
n=184								

Table H1 b) Significant univariable findings, Pakistan (current water habits – social dynamics)

		POSITIVE COUNTS (>0 SACHETS)			ZERO COUNTS (Odds of 0 vs >0 sachets)			
Independent variables	Effect size categories	Rate of average weekly usage (IRR)	Category specific p-value	95% CI	Odds of no sachet use (OR)	Category specific p-value	95% CI	Multiple parameter Wald's test
CURRENT WATER HABITS								
n=223								
Proportion of household consuming treated water in past week	everyone (85%) / mixed (15%)	**0.83**	0.003	0.73-0.94	**2.13**	0.001	1.4-3.3	<0.0001
Untreated water use in past week	no (69%) / yes (31%)	**0.87**	0.001	0.8-0.94	**1.71**	0.003	1.2-2.4	0.0001
Use of product for non-drinking purposes in past week	no (62%) / yes (38%)	**1.11**	0.006	1.03-1.2	**0.56**	0.004	0.37-0.83	0.0003
Use of boiling water treatment	no (64%) / yes (36%)	**1.12**	0.006	1.03-1.2	**0.77**	0.22	0.51-1.2	0.015
SOCIAL DYNAMICS								
Whether household members agree about product or differ	all agree (89%) / some disagree (11%)	**1.02**	0.8	0.88-1.2	**2.02**	0.015	1.2-3.6	0.034

Table H2 Significant univariable findings, Zambia

Independent variables	Effect size categories	Rate of average weekly usage (IRR)	Category specific p-value	95% CI	Multiple parameter Wald's test
A PRIORI (n=204)					
Days since visit	continuous (median: 7)	1.05	<0.001		<0.0001
Crossover period (2 in total)	1 (four weeks) / 2 (four weeks)	0.7	<0.001		<0.0001
Product	Pureit (50%) / PoW (50%)	1.02	0.644		0.64
SOCIO-ECONOMIC (n=204)					
Household size	continuous (median 6)	1.02	0.052	01/01/04	0.052
Main language	Nyanja (60%) / Bemba (23%) / Mix (17%)	1.14	0.068	0.99-1.3	0.062
		0.92	0.32	0.77-1.1	
Proportion of literate members in household	half or less (64%) / more than half (36%)	0.87	0.019	0.77-0.98	0.019
PAST WATER-RELATED EXPERIENCE					
Whether head of household grew up treating water (n=192)	no (54%) / yes (46%)	1.16	0.017	1.03-1.3	0.017
Whether household suffered because of water in past (n=194)	no (56%) / yes (44%)	0.89	0.08	0.79-1.01	0.08
PRODUCT FEEDBACK					
Product rating (likability)	highest (62%0 / mid (30%) / lowest (8%)	0.88	0.028	0.78-0.99	0.013
(n=197)		0.8	0.015	0.67-0.96	
Whether product taste acceptibilty changed*	never noticed (31%) / always (43%) / less with time (23%) / more (4%)	0.87	0.05	0.76-1	0.088
(n=191)		0.82	0.013	0.71-0.96	
		0.88	0.23	0.71-1.08	
CURRENT WATER HABITS					
Use of product for non-drinking purposes in past week (n=198)	no (45%) / yes (55%)	1.24	<0.001	1.1-1.4	0.0004

H-2 Study findings in light of IBM-WASH factors

Neighbourhoods in Pakistan, and household size in both study sites represent contextual variables, at the structural and household level, respectively. Water-related habits, and past water-related experiences are psychosocial factors at the household and habitual levels, though could arguably also be classified as contextual, as this dimension includes factors that could typically not be affected by an intervention(Dreibelbis et al., 2013). Perceived need and water-related risk factors are noted in much of the behaviour change literature, though often focussed on at the individual-level (Mosler, 2012; Rosenstock et al., 1988), in contrast to our study where they played out largely at a community level. Interpersonal factors, including household reinforcement and trust due to the relationship with the team and social networks, are psychosocial factors at the interpersonal level. Water-related habits, and past water-related experiences are psychosocial factors, though were observed at the habitual level, household level, and community level (i.e in each study site). The least significant of the three dimensions in our analysis was the Technological one, despite our study having included substantial questions on product feedback. This included product likability ratings, and demonstrations of usage, which could arguably be seen as a proxy for self-efficacy, a major factor in much of the behaviour change literature (Mosler, 2012; Rosenstock et al., 1988). On the other hand, one of the most significant factors leading to greater adherence in both study sites was the use of treated water for non-drinking purposes, a technological factor at the household level. Another factor strongly associated with lower adherence was untreated water consumption, which is strictly speaking a psychosocial factor within water-related habits, but could also be considered to be a technological factor (or closely correlated to them), as an indicator of non-adherence.

APPENDIX I: REFERENCES

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